CHAP

Community Health Accreditation Program, Inc. 1300 19th Street NW, Suite 150 Washington, DC 20036 t: 202-862-3413 f: 202-862-3419 web: www.chapinc.org

March 14, 2006

Patricia Harris Executive Officer California State Board of Pharmacy 1625 N. Market, Suite N219 Sacramento, CA 95834

RE: Re-Application for Board Approval under Senate Bill 293, Section 4127.1d

Dear Ms. Harris:

The Community Health Accreditation Program, Inc. (CHAP) is re-applying to California State Board of Pharmacy for approval to exempt pharmacies from licensure under requirements established by Senate Bill 293, Section 4127.1d of the Business and Professional Code.

Included is CHAP's current response to the evaluation factors identified by the Licensing Committee as required in section 4127.1. CHAP supportive documentation is attached as Appendix I-III. Included also is a cross-walk from CCR Section 1751 (revised) Sterile Compounding Regulations to CHAP CORE Standards 2004 and CHAP Pharmacy Standards 2004/1005.

Thank you for consideration of this re-application.

Please contact me if you need further documentation.

Sincerely yours,

Terry A. Duncombe, RN, MSHA

President & CEO

CHIP

RE-APPLICATION TO THE CALIFORNIA STATE BOARD OF PHARMACY FOR

APPROVAL TO EXEMPT PHARMACIES FROM LICENSURE UNDER REQUIREMENT ESTABLISHED BY
TITLE 16 CALIFORNIA CODE OF REGULATIONS
SECTION 1751 – REVISED
(SECTION 4127, 4127.7 OF THE BUSINESS AND PROFESSIONS CODE)

SUBMITTED BY:
COMMUNITY HEALTH ACCREDITATION PROGRAM, INC. (CHAP)
1300 19th Street, Suite 150
Washington, DC 20036

Factor 1. Periodic Inspection

The Community Health Accreditation Program, Inc. (CHAP) conducts a full comprehensive site visit to pharmacies at least once every three years. Every standard for Core and Pharmacy, is assessed during these site visits. Based upon the performance of the pharmacy and the findings, particularly in the Quality Standards (Section II of each set of standards), the CHAP Board of Review may determine to require a return site visit within 6-12 months to focus on and assess compliance with the required actions cited during the site visit. The Accreditation Process is described in the CHAP informational brochure, which is included as Appendix I.

Factor 2. Documented Accreditation Standards

CHAP accredits all types of pharmacies, including pharmacies that compound sterile products. CHAP currently uses two sets of standards to assess pharmacy services: Core 2004 (overall administrative standards) and Pharmacy 2004/2005 (service specific standards) Standards of Excellence. The Standards are included as Appendix II. Each of the standards contain language further requiring compliance with State and Federal statues governing pharmaceutical practice. Each pharmacy is assessed during a site visit for compliance with CHAP standards as well as federal and state-specific regulations. In addition, CHAP standards are consistent with the professional standards of practice as defined by the American Society of Health System Pharmacy and published in Best Practices for Health-System Pharmacy, ASHP, and referenced for assessment.

Subsequent to CHAP's initial application to the California State Board of Pharmacy in 2003, CHAP revised its pharmacy standards and formatted them in a tiered structure with basic standards applicable to all pharmacy services plus add-on standards with additional requirements applicable to specialized pharmacies such as infusion pharmacies. The CHAP 2004/2005 Pharmacy Standards are consistent with the intent of USP 797, incorporate requirements from Medicare Modernization Act, Part D, and are consistent with California State Board of Pharmacy Sterile Compounding Special Licensure regulations.

CHAP assesses standards in terms of "Met" or "Not Met." The standard must be met in full to be assessed as "Met." If any element of the standard is not met, the standard is assessed as "Not Met," and a "Required Action" is written for that Standard. Required Actions are actions which the organization is required to perform in order to achieve compliance with CHAP Standards. The Board of Review decision to accredit, deny accreditation or defer accreditation is based upon the number and types of Required Actions identified. CHAP does not use a scoring methodology for assessing compliance and determining accreditation decisions

An organization is **accredited** if the site survey findings provide evidence that the organization is in substantial compliance with CHAP standards. An organization is **deferred** in initial accreditation based upon evidence that the organization is not in substantial compliance with the CHAP Standards but has evidence that they possess the ability to come into substantial compliance within a reasonable time frame, not to exceed one year from the deferral date. A full site visit will subsequently be conducted to determine compliance with CHAP standards. An organization is **denied** initial accreditation based upon evidence that the organization is not in substantial compliance with the CHAP Standards and lacks adequate structure and function to correct the deficiencies in a timely manner. The organization has the option of reinitiating the application process six months from the date of the initial site visit. Other Board of Review accreditation decisions include **formal warning** and **termination**.

Factor 3. Evaluation of Surveyor's Qualifications.

CHAP requires pharmacy site visitors to have the following minimum qualifications:

- 1. Currently licensed Registered Pharmacist with a minimum Bachelor of science in pharmacy.
- 2. Five years experience in pharmacy management.
- 3. Current experience in community-based or infusion-based compounding pharmacy services.
- 4. Demonstration of strong analytical, consultative, conflict resolution, mediation and written and written and verbal articulation skills.
- 5.. Demonstration of experience with an accreditation process.
- 6. Successful completion of a CHAP Site Visitor Training Program and four practicum site visits.

CHAP currently has four pharmacy site visitors with professional pharmacy experience ranging from 12-40 years, with clinical management experience ranging from 9-30 years, with one holding a Masters degree and two holding Doctor of Pharmacy degrees. Each one of CHAP's pharmacists is currently employed in active pharmacy services.

The CHAP Board of Review (BOR) has a pharmacist position appointed by the Board of Directors. That pharmacist is responsible for reviewing and assessing Pharmacy Site Visit Reports to assure consistent citation of pharmacy standards. The BOR Pharmacist is also responsible for assessing new or revised standards as part of the BOR and recommending adoption to the Board of Directors.

The CHAP Board of Directors (BOD) has a pharmacist member elected by the Board of Directors who is also a resource for pharmacy-industry related issues.

Factor 4. Acceptance by Major California Payors

CHAP is accepted by all California payors as well as all national payors.

Factor 5. Unannounced Inspection of California Accredited Sites

CHAP understands that the State Board of Pharmacy will conduct unannounced inspections of two or more California accredited pharmacy sites to assess for satisfactory compliance with California law and good professional practice.

Factor 6. Board Access to Accreditor's Report on Individual Pharmacies

CHAP provides a written report to each pharmacy following a site visit and review and determination by the Board of Review. Each of the pharmacies accredited by CHAP has a copy of the written report available on site.

Factor 7. Length of Time the Accrediting Organization Has Been Operating

CHAP has been accrediting organizations since 1965. CHAP was the first national accreditation organization to accredit community-based health organizations in the United States and was the first organization awarded deeming authority by CMS (formerly HCFA) for home health in 1992 and for hospice in 1999. CHAP Pharmacy Standards are recognized by JCAHO as being comparable in definition and expectations.

Factor 8. Ability to Accredit Out-of-State Pharmacies.

CHAP currently accredits organizations throughout the United States, Hawaii and Puerto Rico and is able to accredit pharmacies regardless of state of operation.

CHAP currently accredits 63 Pharmacies located in 23 states. CHAP has 16 pharmacies that have applied for accreditation and are in the process of contract execution or currently undergoing the self-study process.

Additional Questions:

1. What companies are accredited for Pharmacy by CHAP in California?

Accredited:

Factor Support Network Pharmacy, Inc., Camarillo

Applied for Accreditation:
Valu-Med Pharmacy, Anaheim

Pharmaco d/b/a Premier Infusion Care, Torrance

2. Is CHAP accreditation comparable to JCAHO?

JCAHO has completed an evaluation of CHAP standards which resulted in their recognition of general comparability between the standards of our two organizations.

3. What is an example of an evaluation sheet and report?

The CHAP Site Visitor Work Book is used for evaluating compliance with the CHAP Standards. A Board of Review Site Visit Report is generated from the commendations, recommendations and required actions cited in the Site Visitor Work Book. The Board of Review reviews the Site Visit Report and completes a Summary Data Collection Tool in order to assure a logical and focused review of Site Visit Reports and to promote consistency in the interpretation of site visit findings by each reviewer. Consistency in the interpretation of site visit findings by the Board of Review drives the decision making process. A sample of the Site Visitor Work Book, the Board of Review Site Visit Report format and the Board of Review Summary Data Collection Tool are included as Appendix III.

CROSSWALK OF CHAP PHARMACY STANDARDS 2004/2005 EDITION TO CALIFORNIA CODE OF REGUALATIONS TITLE 16, SECTION 1751 (REVISED) and SECTIONS 4127, 4127.7 STERILE COMPOUNDING SELF-ASSESSMENT COMMUNITY HEALTH ACCREDITATION PROGRAM, INC.

INT DESCRIPTION	CHAFSTANDARD
Title 16, Section 1751 (Revised)	
CCR 1751: COMPOUNDING AREA	
s are made of non-porous cleanable surfaces.	DⅢ.4a.3
	DII.8a.6,8, DIII.4a.5
w hoods & clean room equipment are certified annually.	DIII.4f
ironment.	DⅢ.4a.7a DⅢ.4a.7c
There is a sink with hot and cold running water.	DIII.4a.2
neet the storage requirements for all material requiring	DIII.4a.7b
	рш 4° рШ 4һ 1
CCR 1/51.01: FACILITY AND EQUIPMENT STANDARDS FOR STERME HATCHADE.	
On or after July 1, 2005, the following shall apply to any pharmacy compounding sterile injectable	
n an ISO class 7 (class 10,000) clean room (with	DШ.4a, DШ.4b.1
positive air pressure differential relative to adjacent areas)	
ľ	
A ISO class 5 (class 100) clean room with positive air pressure differential relative to adjacent areas	DIII.4a, DIII.4b.1
A harrier isolator that provides a ISO class 5 (class 100) environment for compounding	<u> DШ.4а, DШ.4а.1, DШ.4b.1, DШ.4е</u>
	DII.7c.2, DII.8f.5, DIII.4b.5, DIII.4e,
pu	DⅢ.4g
are properly attired.	DП.8а.4, DП.8f.2, DШ.4g
be easily	DII.4a.3, DII.4a.7c, DII.8a.7
cleaned and disinfected.	
	DII.7c.2, DII.8f1, DIII.4b2
ceilings, shelves, tables and stools must be disinfected weekly and after any unanticipated even that	
could increase risk of contamination.	

CROSSWALK OF CHAP PHARMACY STANDARDS 2004/2005 EDITION TO CALIFORNIA CODE OF REGUALATIONS TITLE 16, SECTION 1751 (REVISED) and SECTIONS 4127, 4127.7 STERILE COMPOUNDING SELF-ASSESSMENT COMMUNITY HEALTH ACCREDITATION PROGRAM, INC.

CALIFORNIA CODE OF REGULATIONS SELF-ASSESSMENT DESCRIPTION	CHAP STANDARD
Title 16, Section 1751 (Revised)	
CCR 1751 02: POLICIES AND PROCEDURES	
Written policies and procedures associated with the pharmacy's preparation and dispensing of sterile	DLS
injectable products shall include but not be limited to:	
• Compounding, filling, and labeling of sterile injectable compounds	DI.5c.13, DI.5c.18-21
• Labeling of the sterile injectable product based on the intended route of administration and	DII.5e.10, 11
recommended rate of administration.	
• Fourinment and supplies	DI.5c.14, 15
	CL.5d.5, DI.5c.22-23, DII.8d
	DI.5e
	CI.5c.9, CI.5h, CII.5a-g, DI.5c.17,
	PHOLICA PHES DHEAD PHOF 2 A
• The ingredients and the compounding process for each preparation must be determined in writing before compounding begins and must be reviewed by a pharmacist	DII.2b1a4, DII.3c, DII.3u.2, DII.0l.3,4
Written policies and procedures immediately available to all personnel involved in the	CLSi, CIII.1f
compounding activities and Board of Pharmacy Inspectors	
• All personnel involved must read the policies and procedures before compounding sterile	CI.5g.9a-c, CI.5i
injectable products and any additions, deletions, and revisions to the written policies and	
procedures must be communicated to all personnel involved in sterile compounding	
Policies and procedures must address at least the following:	
Staff competency evaluations	CIII.1i, DI.5c.22.23, DII.8f5, DIII.1c,1d
Storage and handling of products and supplies	DI.5c1,3,9
	DI.5c1,7,18, DIII.4c
	DI.5c18, DII.7c2, DII.8f
	DII.8f2, DII.8a.1-10
	DI.5e, DI.5c15, DII.8e
manipulation of sterile products (e.g. laminar air flow workstations, biological safety cabinet, class	
100 clean room, and barrier isolation workstations).	

COMMUNITY HEALTH ACCREDITATION PROGRAM, INC.

CROSSWALK OF CHAP PHARMACY STANDARDS 2004/2005 EDITION TO CALIFORNIA CODE OF REGUALATIONS TITLE 16, SECTION 1751 (REVISED) and SECTIONS 4127, 4127.7 STERILE COMPOUNDING SELF-ASSESSMENT

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	STENIE COMECONDING SELF-PROPERTY	
<u> </u>	CALIFORNIA CODE OF REGULATIONS SELF-ASSESSMENT DESCRIPTION	CHAP STANDARD
	Title 16, Section 1751 (Revised)	
•		DL5c.15, DII.8a.7, DII.8f
	alternation of disinfectants (pharmacies subject to institutional infection control policy may follow that policy).	
•		DI.5e4, DII.8a9,10, DII.8c
	avoid accumulation in the controlled area.	
•	For sterile batch compounding, written policies and procedures must be established for the use of	DII.6a.2,3
•	1	DI.5c18
•		DII.7c2, DIII.4b5
1	Labels to include telephone number of pharmacy (exemption: sterile injectable products dispensed for	DII.5e1
-=	inpatients of a hospital)	
1	Name and concentration of ingredients contained in the product	DII.5e6
	Instructions for storage and handling	DII.5e7, DIII.8d1-3
1	All extotoxic agents shall bear a special label which states "Chemotherapy-Dispose of Properly"	DII.5e9
, ,	CCR 1751.3: RECORD KEEPING REOUIREMENTS	DII.6
<u> </u>	There is an immediately retrievable patient medication profile for each patient.	DIL6
1 1-4	Pharmacies compounding sterile injectable products for future use shall also have records indicating	DII.5e, DII.6a2,3
-	the name, lot number, amount, and date on which the products were provided to the prescriber.	
	Maintenance of records for three years to include:	CI.5h2,3
1	Training and competency evaluation of employees in sterile product procedures.	CI.5h8, CIII.1g13
		DII.4a,b,c
•		DII.6a3d, DIII.4b4, DIII.4f
	according to written policies and procedures.	
	• Other facility quality control logs specific to the pharmacy's polices and procedures are	DIII.4b1-5
	maintained (e.g. cleaning logs for facilities and equipment)	r r
	 Inspection records for expired or recalled pharmaceutical products or raw ingredients exists. 	DI.5c25, DII.8c1
	 Preparation records including the master work sheet, the preparation work sheet and records of 	DII.6a3d, DII.4a-c, DII.7c2, DIII.4b5
	end-product evaluation	
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CROSSWALK OF CHAP PHARMACY STANDARDS 2004/2005 EDITION TO CALIFORNIA CODE OF REGUALATIONS TITLE 16, SECTION 1751 (REVISED) and SECTIONS 4127, 4127.7 STERILE COMPOUNDING SELF-ASSESSMENT COMMUNITY HEALTH ACCREDITATION PROGRAM, INC.

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CALLFORNIA CODE OF REGULATIONS SELF-ASSESSIMENT DESCRIPTION	CHAI STANDAM
CCD 1751 4 ATTIRE	
When preparing extotoxic agents, gowns and gloves are worn	DII.8a.4
Clean room garb consists of a low-shedding coverall, head cover, face mask, and shoe covers must be	DI.5e, DI.5e.4
worn inside the designated area at all times.	
Clean room garb must be donned and removed outside the designated area	DI.5e, DI.5e.4
Hand, finger and wrist jewelry must be removed. If jewelry cannot be removed, the jewelry must be	DI.5e, DI.5e.4
thoroughly cleaned and covered with a sterile glove	
Head and facial hair must be kept out of the critical area or be covered	DI.5e, DI.5e.4
Protective gloves made of low-shedding materials are required	DI.5e, DI.5e.4
Note: Requirements may not apply if a barrier isolator is used to compound sterile injectable	
products from one or more non-sterile ingredients.	
CCR 1751.5: TRAINING OF STAFF, PATIENT AND CAREGIVER	
Consultation shall be available to the patient and/or primary caregiver concerning proper use of sterile	DII.5i, DII.5j, DII.8d
injectable products and related supplies furnished by the pharmacy	
The pharmacist-in-charge shall ensure all personnel engaged in compounding sterile injectable drug	СШ.11, DШ.1с, DШ.1d, DШ.1g
products shall have training and demonstrate on-going competence in the safe handling and	
compounding of sterile injectable drug products including cytotoxic agents.	
Records of training and demonstrated competence shall be available for each individual and shall be	CI.5h.8
retained for 3 years beyond the period of employment.	
Pharmacies must have an established and follow a written program of training performance evaluation	DIII.1g
designed to ensure that each person working in the designated area has the knowledge and skills	
necessary to perform their assigned tasks properly.	
ss the	DII.8f, DIII.1b10, DIII.1c, DIII.1d
calculations/terminology, sterile products compounding documentation, quality assurance procedures,	•
aseptic preparation procedures, proper gowning and gloving techniques, general conduct in the	
controlled area, cleaning/sanitizing and maintaining equipment used in the controlled area,	
sterilization techniques, container, equipment and closure system selection.	
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CROSSWALK OF CHAP PHARMACY STANDARDS 2004/2005 EDITION TO CALIFORNIA CODE OF REGUALATIONS TITLE 16, SECTION 1751 (REVISED) and SECTIONS 4127, 4127.7 STERILE COMPOUNDING SELF-ASSESSMENT COMMUNITY HEALTH ACCREDITATION PROGRAM, INC.

CALIFORNIA CODE OF REGULATIONS SELF-ASSESSMENT DESCRIPTION	CHAP STANDARD
Each person assigned to the controlled area must successfully complete practical skills training in	DII.8a, DIII.1b.6,10, DIII.1g
Evaluations must include written testing and a written protocol of periodic routine performance checks involving adherence to asentic area policies and procedures.	РШ.1 d.1-5
Each person's proficiency and continuing training needs must be reassessed every 12 months.	DШ.1с.2, DШ.1d
Results of staff assessments must be documented and retained in the pharmacy for three years.	СШ.1g.8,9, СШ.1і.1-4
CCR 1751.6: DISPOSAL OF WASTE MATERIAL	
Pharmacies compounding sterile injectable products shall have written policies and procedures for the	CII.7e.4, CII.7e.5, DI.5e.4, DII.8a.10
disposal of infectious materials and/or other materials containing cytotoxic residue.	
Procedures shall include cleanup of spills and shall be in conformance with local health jurisdiction.	DП.8с.2, DIП.4а
CCR 1751.7: OUALITY ASSURANCE AND PROCESS VALIDATION	
Each pharmacy shall have a documented on-going quality assurance program that monitors personnel	DII.5e, DII.7, DII.8a.1-10, DII.8c, DII.8f
performance, equipment, & facilities.	
The end product shall be examined on a periodic sampling basis as determined by the pharmacist-in-	DI.5c.18, DII.7c, DIII.4b.5
charge to assure that the product meets required specifications.	
The quality assurance program shall include:	
• Cleaning & sanitization of the parenteral medication preparation area.	DII.8a7, DII.8d.1, DIII.1f.1-5, DIII.4b.1-5
Written documentation that the end product has been tested on a periodic sampling basis for	DII.7b, DII.7c.2, DIII.4b.5
microbial contamination & steps taken in the event that testing for contamination proves	
positive.	
The storage of compounded parenteral products in the pharmacy and periodic	DIII.4c, DII.8d.2
documentation of remperator temperature.	DI 50.75 DH 80.1
 Steps taken in the event of a drug recall. 	DI.JC.2.J, DII.0C.1
Written justification of the chosen expiration date for compounded injectable drug products.	DII.5e.11
Process Validation:	
Each individual involved in the preparation of sterile injectable products from one or more non-sterile ingredients must successfully complete a validation process before being	DII.8f.2,4,5, DIII.1b.10, DIII.1d.1-5, DIII.1c
allowed to prepare sterile products.	

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CROSSWALK OF CHAP PHARMACY STANDARDS 2004/2005 EDITION TO CALIFORNIA CODE OF REGUALATIONS TITLE 16, SECTION 1751 (REVISED) and SECTIONS 4127, 4127.7 COMMUNITY HEALTH ACCREDITATION PROGRAM, INC. STERILE COMPOUNDING SELF-ASSESSMENT

CALIFORNIA CODE OF REGULATIONS SELF-ASSESSMENT DESCRIPTION	CHAP STANDARD
Title 16. Section 1751 (Revised)	
• The validation process shall be carried out in the same manner as normal production, except	DII.8f.5, DIII.4e.1
that an appropriate microbiological growth medium is used to test the sterility of the final	
product.	
• The same personnel, procedures, equipment, and materials are involved.	CIII.11-4, DII.8f.1-5
Completed medium samples must be incubated.	DIII.7c.2, DII.8f.5
If microbial growth is detected, then the sterile preparation process must be evaluated,	CII.6d, CII.6e, CII.6g, DII.7c.2
corrective action taken, and the validation process repeated.	
Personnel competency must be revalidated at leaset every 12 months, whenever the quality	DIII.1d.1-5
assurance program yields an unacceptable result, or whenever improper aseptic techniques	
are observed.	
The validation and revalidation process must be documented.	CIII.1g.8a-b,15, CIII.1i.4, DII.6a.3d
CCR 1751.9: REFERENCE MATERIALS	
There must be current and appropriate reference materials regarding the compounding of sterile	DI.2d, DIII.1g
Injectable products rocated in or immediately available to the products:	

CHAP ... creditation Is A Process Not An Event

The 4 Steps to the CHAP Accreditation Process

Step 1 - Application and Confract

 Organization completes the Application for Accreditation and submits to the CHAP office.

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- CHAP first determines the organization's eligibility for accreditation.
- CHAP then determines the number of site visit days necessary to assess the organization.
- Based on the information provided, CHAP establishes the fee for accreditation.
- CHAP develops a contract for accreditation which outlines the duties and responsibilities for both parties.

Step 2 - Self Study

 The Self Study is a tool which allows the organization to do a comprehensive internal evaluation against the CHAP Standards of Excellence.

COARDITATION PROGRAM

 Organization has three to six months from the date of the signed contract to submit the completed self study.

Step 3 - Site Visit

- Announced or in some cases must be unannounced
- Length of site visit & composition of the team is contingent upon the organization's size, complexity of products, and services provided
 - CHAP site visitors are health care professionals with 5 or more years of experience in their area of expertise

Step 4 - Determination of Accreditation Status

- Board of Review (BOR) members are industry experts
- Review all site visit reports for accuracy and findings
- Determine accreditation status for all organizations

Service-Areas



Note: Map not to scale

Really Only One Choice

For additional information, please feel free to contact CHAP at:

Phone: 800-656-9656
E-mail: info@chapinc.org
Web Site: www.chapinc.org

The irst Nationally Recognized Community Based Accreditation Organization

Community Health Accreditation Program, Inc. (CHAP), the first national accrediting organization to receive "Deeming Authority" from CMS, was established in 1965 as a joint venture between American Public Health Association (APHA) and the National League for Nursing (NLN). In 1988, CHAP became a wholly-owned subsidiary of the NLN and in 2001 became an independent non-profit corporation governed by a voluntary Board of Directors.

Members of the CHAP Board of Directors represent consumers, providers, and experts in the home and community health care industry

The CHAP philosophy assures the availability of quality home and community based health care through the voluntary commitment to accreditation by the applicant organizations. This is essential as home and community health care becomes the centerpiece of the health care industry. It is CHAP's firm belief that the accreditation process should separate excellent organizations and programs from those meeting only minimal

Accreditation Plays An moortant Role In Coday's Healthcare System

CHAP accreditation publicly certifies that an organization has voluntarily met the highest standards of excellence for home and community based health care. CHAP has **Standards of Excellence** driven by considerations of quality, client outcomes, adequate resources, and long-term viability. The CHAP goal is to assist all types of community based health care organizations to:

- Strengthen internal operations
- Promote continuous quality improvement
- Promote positive client outcomes
- Promote consumer satisfaction
- Cost effectively meet organizational needs
- Maintain organizational viability
- Assure public trust in community based health care services and products

Eligibility For Accreditation:

- The organization must have legal authority to operate.
- Provide one or more of the services or product lines listed on the next page.

CHAP accredits over 1,500 community based organizations.

The CHAP **Standards of Excellence** provide guidance and reality-based criteria for the evaluation of an organization. These criteria are based on four key "underlying principles" which drive each set of CHAP standards. The four guiding principles are:

- The organization's structure and function consistently supports its consumer oriented mission.
- The organization consistently provides high quality services and products.
- . The organization has adequate human, financial, and physical resources to accomplish its stated mission.
 - 4. The organization is positioned for long-term viability.

CHAP maintains standards of excellence and provides accreditation for the following services:

- Home Health
- Hospice
- Home Medical Equipment
- Home Infusion Pharmacy
- Infusion Therapy Nursing
- Public Health
- Community Nursing Centers
- Private Duty Services
- Home Care Aide Services
- Supplemental Staffing Services



CORE

STANDARDS OF EXCELLENCE

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Core Standards CHAP, Inc.

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2004 Edition

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INTRODUCTION TO CHAP CORE STANDARDS

The Community Health Accreditation Program, Inc. (CHAP, Inc.) is an independent, non-profit accrediting body for community based health care organizations. The types of organizations accredited include: home health, hospice, public health, home care aide services, private duty services, supplemental staffing services, infusion therapy nursing, home medical equipment, pharmacy services, and community nursing centers.

This "first" accrediting body for community based health care organizations in the United States dates back to 1965. A joint venture between the American Public Health Association (APHA) and the National League for Nursing brought to fruition the futuristic view of their respective membership that accreditation was the needed mechanism to recognize excellence in community health practice. In 2001, CHAP became an independent corporation with the purpose of using the accreditation process to elevate the quality of all community-based health care in the United States.

The CHAP accreditation process utilizes the "CHAP Standards of Excellence" that are driven by considerations of management, quality, client outcomes, adequate resources and long term viability.

The goal is to assist all types of community-based health care organizations to:

- Strengthen internal operations
- Promote continuous quality improvement techniques and systems
- Promote consumer satisfaction
- Affirm public trust
- Meet community health needs in a cost efficient and effective manner
- Maintain the viability of community health practice nationwide

CHAP, Inc. is committed to ensuring that home and community based health care providers adhere to the highest standards of excellence and that they maintain compliance with the current standards. Ongoing professional assistance and guidance provided by CHAP promotes continuous organizational self-improvement.

CHAP Accreditation publicly certifies that an organization has voluntarily met the highest standards of excellence for home and/or community based health care. Additional benefits of Accreditation by CHAP, Inc. include management consultation of the highest quality, access to a broad network of professional resources, and guidance critical to building intra- and interorganizational collaboration and strength.

Currency and Relevance of Standards

In keeping with its goal of elevating the quality of all community health care in the United States, CHAP, Inc. continually reviews and revises the "Standards of Excellence" to assure currency with the community health care industry. CHAP standards place a strong emphasis on organizational management and client outcomes. They are to be used as a blueprint to build and maintain a highly sophisticated home or community health care organization, thus assuring the viability of the organization.

The 2004 Edition revisions are designed to:

- Establish standards of excellence for a wide variety of home and community-based health care organizations and programs
- Promote ease of application, interpretation and use of standards
- Emphasize the importance of the interests and rights of individual and group consumers of home and community-based health care services
- Strengthen the long-term viability of all types of community-based health care organizations
- Advance the recognition of the importance of home and community-based health care organizations as integral components of the national health care delivery system

The re-engineered CORE Standards of Excellence address the scope and complexity of community-based health care providers in today's health care arena, are generic, and apply to all services and programs accredited by CHAP.

The core standards are used in conjunction with service specific standards to ensure compliance with:

- Federal, state and local regulatory requirements
- Regulatory requirements that address the health and safety of employees and clients

The service specific standards address requirements additional to Core which are unique to the specific service or industry.

Additional Requirements for Medicare-Certified Home Health and Hospice Services

CHAP has received authority from the Centers for Medicare and Medicaid Services (CMS) to deem certified home health services and certified hospice services to be in compliance with the Conditions of Participation (COPs). CHAP's Core/Home Health Standards and CHAP's Core/Hospice Standards contain standards which include the intent of the Medicare COPs for home health and hospice.

The home health agency that elects to receive Medicare Certification through deeming authority from CHAP must comply with CFR 484 Medicare Conditions of Participation: Home Health Agencies. See Appendix I HH for a full text of the home health regulations and a cross walk to the CHAP Standards.

The hospice organization that elects to receive Medicare Certification through deeming authority from CHAP must comply with CFR 418 Medicare Conditions of Participation: Hospice. See Appendix I H for a full text of the hospice regulations and a cross walk to the CHAP Standards.

Underlying Principles

I. Structure and Function

III. Resources

II. Quality

IV. Long Term Viability

Four key "Underlying Principles" (UP) continue to drive each set of the CHAP Standards of Excellence. Sub-categories in each section further define the content.

UP I. THE ORGANIZATION'S STRUCTURE AND FUNCTION CONSISTENTLY SUPPORTS ITS CONSUMER ORIENTED MISSION

- A. Statement of Mission
- B. Organizational Structure And Functional Mechanisms
- C. Organizational Relationships/Chart
- D. Administrative Authority and Responsibility
- E. Organizational Policies
- F. Communication
- G. Ethical Issues
- H. Research Initiatives

UP II. THE ORGANIZATION CONSISTENTLY PROVIDES HIGH QUALITY SERVICES AND PRODUCTS.

- A. Business and Clinical Practices
- B. Client Access to Care, Services and Products
- C. Prioritization of Care Delivery
- D. Coordination, Planning, Implementing, Monitoring, and Evaluating Care and Services Provided
- E. Client Records
- F. Performance Improvement
- G. Safety of Employees and Clients
- H. Complaints

UP III. THE ORGANIZATION HAS ADEQUATE HUMAN, FINANCIAL, AND PHYSICAL RESOURCES TO ACCOMPLISH ITS STATED MISSION AND PURPOSE.

- A. Human Resources Support Workload Demand
- B. Contracts
- C. Financial Management
- D. Financial Information System
- E. Physical Facilities
- F. Management Information System

UP IV. THE ORGANIZATION IS POSITIONED FOR LONG TERM VIABILITY.

- A. Strategic Planning
- B. Annual Evaluation of the Organization

As you study and apply these standards to your own organization, give consideration to the following "THEMES" that flow through all sections of the CHAP Standards of Excellence and Self Studies.

Composition of a Standard

Each standard statement may be comprised of four (4) parts.

- 1. Standard statement A blueprint for success that recognizes excellence
- 2. Criterion A statement that defines in detail the requirements of the standard
- 3. Element A component of each criterion that delineates requirements
- 4. Sub-element Additional statements that provide more definition of selected elements.

Examples
Standard:CI.1
Criterion:CI.1a
Element:1)
Sub element:(a) (not all standards have sub-elements)

Main Sources of Evidence

S = Surveys

Substantiation of Findings

 $\begin{array}{ll} D = \ Documents & Clarification \\ I = \ Interviews & Verification \\ O = \ Observations & Quantification \end{array}$

Evidence Guidelines

The Standards are formatted with relevant Evidence Guidelines on pages opposite the standards. The evidence guidelines are not standards or criteria. They are intended to provide guidelines and examples of evidence to the organization and to the CHAP site visitor which may be used to determine organizational compliance with the standards. The letter preceding each evidence guideline identifies one of four sources of information to be used by the site visitor in the accreditation process: D, I, O, S.

Core Standards CHAP, Inc.

The Site Visit Report

The Site Visit Report is a legal document that states the level of compliance with the CHAP Standards of Excellence. The composition of the report includes a brief organizational profile, statements of organizational strengths and challenges and the written citations.

Citations include:

Commendation:

A statement indicating that the organization has significantly exceeded the

requirements of a specific standard or criterion.

Required Action:

A statement indicating partial or total non-compliance with a CHAP

standard or criterion. Organizations are required to make changes to comply

with CHAP standard or criterion.

Recommendation:

A statement of advisement that identifies a potential problem related to a

standard or criterion that may increase in scope and severity if not

addressed. Organizations are not required to make changes but should give

serious consideration to the recommendation.

Medicare Deficiencies for Home Health and Hospice Organizations:

Tag Items:

Identifiers used by CMS that indicate non-compliance with one or more Medicare Conditions of Participation or Standards are defined as Tag Items.

Tag Item designation applies only to Home Health and Hospice Organizations.

- G-Tags are specific to Home Health
- L-Tags are specific to Hospice

Tag Item designations are used in the Site Visit Report and on all CMS required documents for deemed organizations.

THE PROCESS REQUIRED TO ACHIEVE CHAP ACCREDITATION

CREATES PROFESSIONAL REWARDS FOR YOUR ORGANIZATION.

Core

Abbreviations

Common abbreviations used throughout the CORE Standards include:

ADA Americans with Disabilities Act

P&Ps Policy(ies) and Procedure(s)

Admin. Administration

TO Table of Organization

CDC Centers for Disease Control

TB Tuberculosis

and Prevention

FDA Federal Drug Administration

GB Governing Board

HBV Hepatitis B Vaccine

MC Medicare

MD Medicaid

MDA Medical Device Act

Mgmt. Management

N.B. "Note Well"

OSHA Occupational Safety and Health Act

CI.

THE ORGANIZATION'S
STRUCTURE AND FUNCTION
CONSISTENTLY SUPPORT
ITS CONSUMER ORIENTED
PHILOSOPHY, MISSION AND PURPOSE

- **D DOCUMENTATION**
- I INTERVIEW
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- S SURVEY

CI.1

- D: Current Mission statement includes a consumer focus and orientation to quality. (CI.1)
- Consumers are defined as individuals, groups and D: communities. (CI.1)
- Governing body minutes document actions taken on D: the Mission:
 - a) Review and approval at least every 36 months
 - b) Revisions and updates as applicable (CI.1b)

Page A

- CI.1 Published mission statements clearly identify a commitment to providing high quality services and products which address consumer needs as an organizational priority.
 - CI.1a Programs and services provided reflect the organization's written mission.
 - CI.1b The mission statement is reviewed, revised as indicated, and approved by the governing body at least every 36 months.

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CI.2

- D: Legal documents, specific to the organization, delineate applicable elements of CI.2b which may include: partnership agreement, articles of incorporation, bylaws, state charter, state licensure, tax license, trade name registration, business license, amendments, medicare certification and special waivers.
- D: Note: Governing Body may be a governmental entity.(CI.2c)
- D & I: Name, address, credentials and professional/business affiliation of each member is identified. (CI.2d)

Note: Owner/Operator of a business may constitute the governing body. Governmental Boards of Health may be advisory in nature and/or may be elected or appointed officials.

D &I: New member orientation is validated in writing. Governing body members describe the orientation experience and articulate key issues affecting the organization. (CI.2e)

Note: Independent owner(s) may only have principal(s) as governing body, and orientation in CI.2e may not apply.

- I: Governing body members articulate responsibilities and describe the types of actions taken by the board. (CI.2f)
 - Note: Selected elements may not apply to owner/operator businesses, i.e., selecting the chief administrator.
- D: Current signed and dated annual disclosure statements are on file for all governing body members and executive staff. (CI.2g)
- D &1: Governing body members confirm adherence by governing body members to legal documents which may describe notice of scheduled and special meetings, attendance requirements at meetings, appointment of officers, terms of office, committee structure and function, quorum determination. (CI.2h)
- D: Governing body minutes reflect agenda items, discussion, and action taken. (CI.2i)

Note: Closed sessions are to be documented and distributed/filed per organizational policy.

Note: The Medicare Certified home health agency must comply with CFR 484.12, 484.12(c), 484.14(b), 484.14(i), 484.16, 484.52. See Appendix I HH for a full text of the regulations and a cross-walk.

Note: The Medicare Certified hospice organization must comply with CFR 418.50(c), 418.52, 418.72. See Appendix IH for a full text of the regulations and a crosswalk.

- CI.2 The organization has the structure and functional mechanisms necessary to support and accomplish its stated mission.
 - CI.2a The organization has the legal authority to operate and is in compliance with local, state and federal regulations.
 - CI.2b The applicable governance structure is defined in legal documents specific to the organization.
 - CI.2c An identified governing body assumes full legal authority, responsibility, and accountability for organizational performance; appoints a qualified administrator and designates advisory group membership as applicable.
 - CI.2d The governing body is made up of individuals with relevant expertise, business acumen, and professional relationships specific to the stated mission of the organization.
 - CI.2e Governing body members are oriented to the organization and are knowledgeable and responsive to key issues affecting the organization.
 - CI.2f The governing body carries out responsibilities specific to the organization including:
 - 1) Establishing policies consistent with organizational mission
 - 2) Approving new and/or revised policies and procedures as indicated and necessary
 - 3) Holding management accountable for the fiscal solvency of the organization and adequacy of financial resources
 - 4) Approving budgets and capital expenditures
 - 5) Selecting and evaluating the chief administrator
 - 6) Evaluating organizational performance
 - 7) Developing and approving strategic plan
 - 8) Reviewing legal and business documents in light of real or potential changes to the organization on a periodic basis but not less frequently than every 36 months:
 - (a) Articles of incorporation
 - (b) Bylaws
 - (c) Legal agreements
 - C1.2g Annually, the members of the governing body and executive staff provide written disclosure of all professional or personal relationships or interests, direct or indirect that might present a conflict of interest. Statements are on file in the office.
 - CI.2h The governing body complies with organizational bylaws or other legal documents.

2004 Edition

CI.2i Accurate, complete, and signed minutes are kept of all official meetings of the governing body, document actions taken, are distributed in accordance with organizational policy, and are retained for minimum of five (5) years or consistent with state regulations.

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CI.3

- D: A current organizational chart reflects lines of authority and accountability for all personnel. (C1.3a)
- D: Amendments to the organizational chart are documented as applicable. (CI.3b)
- I: Staff members are familiar with the organizational chart and state their individual lines of authority and accountability. (CI.3c)

Note: The Medicare Certified home health agency must comply with CFR 484.12, 484.14. See Appendix I HH for a full text of the regulations and a cross-walk.

- CI.3 Intra-organizational relationships are clearly defined.
 - CI.3a A current organizational chart delineates the lines of authority and accountability of all personnel.
 - CI.3b The organizational chart is reviewed and changed as needed.
 - CI.3c Personnel understand and use the organizational structure as outlined in the organizational chart.

- **D DOCUMENTATION**
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CI.4

- D: Current job descriptions are on file for administrative and management positions. (CI.4a, b)
- D: CEO/Administrator/Management resumes validate experience, knowledge, and qualifications required for the job. (CI.4b)

Note: This standard may pertain to the Chief Health Care Administrator in Public Health Organizations.

- D: Written policy and procedure defines assignment of administrative responsibilities in the absence of the CEO/Administrator. (CI.4c)
- I: Designated alternate to the CEO/Administrator understands his/her role and describes experiences specific to the alternate role. (CI.4c)
- I: CEO/Administrative and Management personnel describe their respective areas of responsibility. (CI.4d)

Note: The Medicare Certified home health agency must comply with CFR 484.12, 484.12(a), 484.14(c). See Appendix I HH for a full text of the regulations and a cross-walk.

Note: The Medicare Certified hospice organization must comply with CFR 418.56(c). See Appendix IH for a full text of the regulations and a crosswalk.

- CI.4 Authority and responsibility for overall administration and management is vested in qualified individuals.
 - CI.4a The chief executive/administrator's credentials include appropriate industry experience and knowledge of applicable local, state and federal laws.
 - CI.4b Qualifications for administrative and management positions are clearly defined in writing and are consistent with the scope of responsibility and the complexity of the organization, and administrative and management personnel have equivalent combinations of education, training and experience to qualify for their assigned responsibilities.
 - CI.4c A qualified individual is designated in writing to be administratively responsible in the absence of the chief executive/administrator.
 - CI.4d Administrative and management responsibilities are clearly defined and delegated as specified and include:
 - 1) Organizing and directing the organization's ongoing operations to assure the availability and provision of care and services
 - 2) Implementing governing body directives and organizational policies and procedures
 - 3) Complying with applicable laws and regulations
 - 4) Recruiting, employing, and retaining qualified personnel to maintain appropriate staffing levels
 - 5) Ensuring adequate staff education
 - 6) Completing performance evaluations on subordinate staff in accordance with organizational policy
 - 7) Directing and monitoring organizational Performance Improvement activities
 - 8) Managing operations in accordance with established fiscal parameters
 - 9) Planning, developing, implementing, administering and evaluating programs
 - 10) Representing the organization to other groups, organizations and the general public
 - 11) Ensuring the accuracy of public information materials
 - 12) Informing the governing body and staff of current organizational, community, and industry trends

- **D DOCUMENTATION**
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CI.5

- I: Management and advisory/governing body members describe process for development, revision and annual review of policies. (CI.5a)
- D: Administrative policies and procedures address the areas delineated in CI.5b.
- D: A written safety program sets the parameters for monitoring environmental conditions and identifying potential hazards/risks in accordance with elements such as biomedical waste management, storage and handling of environmental cleaning supplies, fire safety, preventive maintenance of equipment, reporting of malfunctioning equipment, environmental controls to prevent client or staff accidents and or incidents and safety of clients and employees in the community. (CI.5b)
- D: Operational policies and procedures detail planning, delivery and evaluation of care and include the 16 elements of CI.5c.
- D: Personnel policies address the 9 elements of CI.5d.

Note: The Medicare Certified home health agency must comply with CFR 484.10(d), 484.11, 484.12(b-c), 484.14(e), 484.16, 484.18, 484.18(b-c), 484.48(a-b), 484.52, 484.52(b), 484.55. See Appendix I HH for a full text of the regulations and a cross-walk.

Note: The Medicare Certified hospice organization must comply with CFR 418.50(c), 418.74, 418.74(a,b). See Appendix IH for a full text of the regulations and a crosswalk.

- CI.5 Organizational policies and procedures reflect an emphasis on quality and ethical practice and relate directly to the mission of the organization.
 - CI.5a Policies and procedures are developed, revised, and reviewed annually to assure currency of information.
 - CI.5b Administrative policies and procedures delineate administrative authority and responsibility for governance, planning, financial control and personnel. Policies include at a minimum:
 - 1) Written Disclosure of conflict of interest
 - 2) Public Disclosure of information
 - 3) Responsibilities of ethical issues review group
 - 4) Rights and responsibilities of clients
 - 5) Internal and External Complaint Management
 - 6) Exposure control plan
 - 7) Formal safety program
 - 8) Financial policies and procedures
 - 9) Research activities/investigational studies as applicable.
 - CI.5c Operational policies and procedures form the framework for planning, delivery and evaluation of care and services provided. Policies include at a minimum:
 - 1) Non-discrimination statement addressing admission of clients to service
 - 2) Defined criteria for the acceptance or non acceptance of clients
 - 3) Admission, continuation of service and discharge
 - 4) Standardized assessment process
 - 5) Referral to other providers of care or services
 - 6) Medical orders, verbal orders and physician oversight as applicable
 - 7) Emergency service
 - 8) After hours service
 - 9) Confidentiality of protected health information
 - 10) Emergency/disaster preparedness
 - 11) Health, safety and security of staff during all hours of work
 - 12) Services/products provided directly and under contract
 - 13) Standards of practice for all disciplines as applicable
 - 14) Standards of operation for all products as applicable
 - 15) Infection control
 - 16) Accepted medical term abbreviations
 - CI.5d Personnel policies are developed and revised in response to organizational change and include:
 - 1) Conditions of employment
 - 2) Respective obligations between employer and employee
 - 3) Non-discrimination information
 - 4) Grievance procedures
 - 5) Employee orientation
 - 6) Employee exit interviews
 - 7) Maintenance of health reports and protected employee information
 - 8) Employee record confidentiality and record retention
 - 9) Recruitment, retention and performance evaluation of staff

- **D DOCUMENTATION**
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CI.5 (Continued)

- D: Written TB Exposure Control Plan includes the elements in CI.5e.
- D: Written policy and procedure define the requirements of Medical Device Act reporting. (CI.5f)
- D: Medical Device Act reports, as applicable, are on file in the organization and include validation of submission to the FDA which may include an incident that results in death and when the manufacturer is unknown. (CI.5f)
- D: Written infection control policies and procedures include the elements in Cl.5g.

- CI.5e The organization's written TB Exposure Control Plan is in compliance with the most current Centers for Disease Control & Prevention (CDC) applicable recommendations and requirements for occupational exposure to Tuberculosis. The plan addresses:
 - 1) Definition of employees at risk of occupational exposure to TB
 - 2) Process for identifying suspected or confirmed cases of TB
 - 3) Control of employee exposure when a patient is suspected/confirmed as having infectious TB
 - 4) Provision of education and training to all employees to the hazards of exposure to TB at the time of employment and annually thereafter
 - 5) Pre-employment and subsequent periodic TB screening of employees in accordance with written policy
 - 6) Provision of follow up care to employees exposed to TB
 - 7) Provision of follow up care to employees who convert to active disease
 - 8) Provision of appropriate personal protective equipment when caring for a suspected/confirmed TB client
 - 9) Provision of work practice oversight to minimize occupational exposure to TB
 - 10) Adherence to reporting and record keeping requirements per state and federal law
- CI.5f Organizational policy and procedure address the requirements of the Medical Device Act (MDA) and delineate the mechanisms for reporting incidents, which result in serious injury, illness or death.
 - 1) Reports are filed with the Federal Drug Administration according to regulation
 - 2) A designated person is responsible for ensuring compliance with reporting requirements
 - 3) Criteria for designation of reportable events are clearly defined
 - 4) Written protocols for the investigation of events are clearly defined
 - 5) Investigative activities are initiated on a timely basis
 - 6) Accurate documentation of findings include:
 - (a) Investigative findings
 - (b) Copies of reports sent to the manufacturer
 - (c) Copies of reports to FDA
 - 7) Retention and retrieval of findings and reports
 - 8) In-service education on Medical Device Act reporting is provided to staff on an annual basis
 - (a) Written curriculum outlines describe training content
 - (b) Records of attendance are maintained
- CI.5g Infection Control policies and procedures detail systems designed to promote the prevention and control of infections, monitor the occurrence of infections and evaluate the effectiveness of infection control practices.
 - 1) Current infection control practices and strategies
 - 2) Identification and investigation of breaks in technique
 - 3) Sources of infection:
 - (a) Nosocomial
 - (b) Home acquired
 - (c) Professional exposure
 - 4) Types of infection
 - 5) Modes of transmission of infection

- **D DOCUMENTATION**
- I INTERVIEW
- O OBSERVATION
- S SURVEY

CI.5 (Continued)

- D: Written policy and procedure define the parameters for ensuring the safety, security, and confidentiality of clinical hardcopy, automated, and/or travel records. (CI.5h).
- D: Written policies and procedures define the parameters that ensure the client's right to access client record information and to release client record information. (CI.5h)
- D: Written policy and procedure and local/state /federal regulations dictate the secure retention of all types of clinical records. (CI.5h)
- D: Written policy and procedure details the process for release of information. (CI.5h)
- I: Records administrator or other designated party describes adherence to policy and procedure. (CI.5h)
- I: Staff describe process for accessing policies and procedures. (CI.5i)

- 6) Contributing causes of infection
- 7) Data collection, analysis, and tracking and trending of findings
- 8) Reporting requirements per state and federal regulations
- 9) In-service education for staff
 - (a) Dates and times of programs
 - (b) Curriculum outline of training content
 - (c) Records of staff attendance
- 10) Client and/or family teaching
- 11) Use of personal protective equipment
- 12) Accepted hand hygiene techniques
- CI.5h Administrative, financial, client and personnel records are secured, retained and retrievable in accordance with a formal record retention policy that is in compliance with organizational policy and local, state and federal law.
 - 1) Minutes of all official meetings of the governing body are retained for a minimum of five (5) years.
 - 2) Client adult records are retained for a minimum of five (5) years after provision of service.
 - 3) Client records of minors are retained for a minimum of seven (7) years after the age of majority is reached.
 - 4) Mechanisms for client access and release of client records are defined.
 - 5) Authorization for client record documentation and entry and signature authorization and authentication for automated client record system in accordance with individual state law are defined.
 - 6) Process for maintaining safety and security of client records is defined.
 - 7) Confidential records for employees experiencing an occupational exposure are retained for the duration of employment plus thirty (30) years.
 - 8) Annual training records for exposure prone employees are retained for a minimum of three (3) years.
 - 9) Client records involved in litigation are retained until after settlement.
- CI.5i Staff members have access to policies and procedures.

- **D DOCUMENTATION**
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CI.6

- D: Informational materials, written in different languages are available and provided to clients/families as appropriate. (CI.6a)
- I: Administrative/management personnel articulate cultural diversity in the community population and describe the organization's ability to meet special needs. (CI.6a)
- I: Staff members demonstrate awareness and use of available resource materials, and clients/families verbalize knowledge of pertinent resources. (CI.6a)
- I: Clients/families of different cultures acknowledge receipt of language specific materials and care provided by bi-lingual staff, family members and/or the use of interpreters as appropriate and necessary. (CI.6b)

Note: The Medicare Certified home health agency must comply with CFR 484.12(a). See Appendix I HH for a full text of the regulations and a cross-walk.

- CI.6 Information is provided to clients/families identifying availability of organizational and community resources to assist in meeting client needs
 - CI.6a Language specific written materials, as necessary and appropriate, are available for distribution to client/families.
 - CI.6b Interpretive services are provided, as indicated and necessary, to ensure accurate communication between the client/family/caregiver and other types of health services personnel.

- **D DOCUMENTATION**
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CI.7

- D: Written policy delineates the make up and function of the designated group to review ethical issues. Authority may be self-vested in the governing body, in an independent entity or in an advisory group. (Cl.7a, b)
- I: Administrative/management/staff personnel describe the structure of the ethical group and the process for handling ethical concerns and issues. (CI.7b)
- D: Meeting minutes document discussions of and actions taken by the group, as applicable. (CI.7c)

- CI.7 The organization's business, clinical, disease prevention and health promotion activities are conducted according to ethical standards.
 - C1.7a A group of qualified professionals is designated by the governing body to review ethical issues as they arise.
 - CI.7b Organizational policy and procedure outlines the responsibilities of the group and delineates the process for submitting ethical concerns and issues for action.
 - CI.7c Meeting minutes clearly document group activities and are referred to the governing body for review and final action as indicated and necessary.

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CI.8

- I: Administrative/management personnel describe that careful consideration is given to providing a site for relevant research, that human subjects involved in any part of research activities provide written informed consent, and that specific parameters for protection of participants and confidentiality of personal information are clearly defined. (CI.8a)
- D: Policy and procedure establish the parameters for research initiatives as applicable. (CI.8b)
- D: Current research activities as applicable ensure compliance with CI.8a,b, c, d.
- I: Administrative/management personnel describe current research initiatives as applicable. (CI.8c)
- I: Staff describes use of research knowledge which was integrated into practice as applicable. (CI.8e)

- Cl.8 The organization considers requests for research in the area of community/public health as appropriate.
 - CI.8a A mechanism is in place for reviewing, processing, and approving internal and external research proposals.
 - CI.8b Organizational policy and procedure defines parameters for participation in research activities and investigative studies.
 - 1) Research protocols, as applicable, for internally and externally sponsored activities are on file
 - 2) Potential participants are provided with written information regarding the nature, process, and benefits of the research outcomes
 - 3) Risks associated with the project are clearly delineated
 - CI.8c Organizations participating in research or investigative studies ensure that clients and staff are fully informed.
 - CI.8d Formal written consents for participants in research and/or investigative studies are obtained and retained on file in the organization.
 - CI.8e New knowledge from internal and external research is integrated into practice as applicable.

CII.

CII.

THE ORGANIZATION CONSISTENTLY PROVIDES HIGH QUALITY SERVICES AND PRODUCTS

- **D DOCUMENTATION**
- I INTERVIEW
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- S SURVEY

CII.1

- D: Current Public Disclosure Policy addresses applicable elements of CII.1a.
- D: The Client Bill of Rights includes the elements of CII.1b.
- I: Clients confirm the timely receipt of the Client Bill of Rights and other admission information. (CII.1c)

Note: Advising clients of their rights is not applicable under conditions of emergency/disaster intervention and mass clinics.

D: Documented evidence in the client records confirms receipt of the Client Bill of Rights and other admission information.

(CII.1d)

Note: Advising clients of their rights is not applicable under conditions of emergency/disaster intervention and mass clinics.

I: Clients/families articulate understanding of the information provided and describe how they have found the information to be helpful. (CII.1d)

Note: The Medicare Certified home health agency must comply with CFR 484.10, 484.10(a-e), 484.12. See Appendix I HH for a full text of the regulations and a cross-walk.

Note: The Medicare Certified hospice organization must comply with CFR 418.50(c). See Appendix IH for a full text of the regulations and a crosswalk.

- CII.1 The mission drives the activities of the organization and ensures public disclosure, client rights and ethical standards of business and clinical practice.
 - CII.1a A public disclosure policy defines the availability and accessibility of public information which includes ownership information, statement of the organization's mission, and licensure and accreditation status, as applicable.
 - CII.1b A written Client Bill of Rights is designed to recognize, protect, and promote the right of each client to be treated with dignity and respect.
 - 1) Written policy and procedure defines the rights and responsibilities of clients.
 - 2) Notice of rights is provided to clients in advance of providing pre-planned care.
 - 3) The client is knowledgeable of the right to exercise his/her rights at any time.
 - 4) The organization maintains documentation of compliance of distribution of required information to clients.
 - 5) The client/client's designated representative is authorized to exercise their rights.
 - 6) Confidentiality of the client record/data is maintained by the organization.
 - 7) Access to care/service is based upon non-discrimination.
 - 8) Clients are informed that they have the right to voice complaints/grievances to the organization regarding treatment/care/service without fear of discrimination or reprisal for doing so.
 - 9) The organization provides the client the telephone number for the CHAP hot line, including the hours of operation and the purpose of the hotline to receive complaints or questions about the organization.
 - 10) Clients are informed that they have the right to participate in the development of care and service plans.
 - 11) Clients are informed verbally and in writing of billing and reimbursement methodologies prior to start of care and as changes occur, including fees for services/products provided, direct pay responsibilities, and notification of insurance coverage.
 - CII.1c Written admission documents, provided to the client or the client's representative prior to or at the time of initiation of care/service, ensure organizational compliance with the Client Bill of Rights and other regulatory requirements.
 - CII.1d A reasonable attempt is made and documented to ensure that the client and family understand their rights and responsibilities which are reviewed with the client prior to or at the time of initiation of care and periodically thereafter.

- **D DOCUMENTATION**
- I INTERVIEW
- O OBSERVATION
- S SURVEY

CII.2

- I: Clients/families describe methods used to contact the organization during regular hours of service, after hours, weekends and holidays. (CII.2a)
- I: Professional, technical, and support staff describe coordination and collaboration between disciplines. (CII.2b)
- I: Professional, technical, and support staff describe coordination and collaboration with sub-contract and/or independent contractor providers of care. (CII.2b)
- I: Clinical supervisors and staff describe the on-call system for services after normal organization hours. (CII.2c)
- O: Testing the after hours on call system validates compliance with organizational policy and procedure. (CII.2c)

- CII.2 Care, services, and products are available to and accessible by the client/client representative.
 - CII.2a Care, services, and products are provided within an established time frame, as specified by organizational policy, organizational standards, medical directives or individual physician orders. Consideration is given to client and/or family needs in scheduling and providing care.
 - CII.2b Collaboration and networking with other providers enhance provision of care and services as applicable.
 - CII.2c Supervisory and clinical/service staff demonstrate knowledge of organizational policy and procedure for ensuring delivery of care, services and products to clients.

- **D DOCUMENTATION**
- I INTERVIEW
- O OBSERVATION
- S SURVEY

CII.3

- D: Written information distributed to clients/families address disasters/emergencies as applicable to the organization's service area. (CII.3a)
- I: Clients/families are aware of their responsibilities in the event of an emergency episode. (CII.3a)
- D: Staff are oriented to written protocols that ensure the safety and security of personnel. (CII.3b)
- D: Disaster drills are documented as applicable to the organization. (CII.3c)
- I: Administrative/management staff describe roles and responsibilities of personnel during an emergency episode. (CII.3c)
- I: Staff members at all levels demonstrate awareness of responsibilities to ensure the safety of self and others. (CII.3c)

Note: The Medicare Certified hospice organization must comply with CFR 418.100. See Appendix IH for a full text of the regulations and a crosswalk.

- CII.3 A geographic specific plan defines the protocols for prioritizing the delivery of care and services to clients and protects the safety of staff during disasters, emergencies and/or environmentally challenging situations.
 - CII.3a Detailed written instructions are given to clients and/or family members to ensure an appropriate and timely response on the part of the client and/or family in the event of a natural disaster, inclement weather, and/or other emergent event that might cause an interruption in the provision of services.
 - CII.3b Written protocols define management responsibilities in ensuring the safety and security of staff prior to or during an emergent event.
 - CII.3c Staff are knowledgeable of the practices and procedures relating to emergency preparedness responsibilities and emergent events.

- **D DOCUMENTATION**
- I INTERVIEW
- O OBSERVATION
- S SURVEY

CII.4

- D: Client records document coordination of care activities. including planning, implementation, monitoring and evaluation of care/service as appropriate. (CII.4)
- I: Clinical/service, financial, and operational staff describes collaboration and support among all disciplines and organizational divisions. (CII.4a)
- O: Organizational planning meetings as available and appropriate. (CII.4a)

Note: The Medicare Certified home health agency must comply with CFR 484.14(g). See Appendix I HH for a full text of the regulations and a cross-walk.

- CII.4 Inter and intra organizational coordination is evident in the planning, implementation, monitoring, and evaluation of care and services provided.
 - CII.4a Coordination between the clinical/service, financial, and operational components of the organization is evident.

- D DOCUMENTATION
- I INTERVIEW
- O OBSERVATION
- S SURVEY

CII.5

- I: Professional, technical, and support staff describe protocols that protect client/family information regarding confidentiality of information, use of travel record and transport and storage of travel record. (CII.5a).
- I: Office staff describe ongoing security of client record information. (CII.5a)
- I: Staff is knowledgeable of the client's right for access to and release of client information. (CII.5a)
- O: Active and inactive client records are maintained in a secure area during working and non-working hours that is inaccessible to unauthorized individuals. (CII.5a)
- S: Random sample of client records reviewed provides evidence of compliance with organizational policy, standards and regulatory requirements. (CII.5c,d)
- O: Automated client record systems include safeguards. (CII.5e)
- I: Client records administrator describes process for ensuring consistent, ongoing validation and protection of automated records data including prevention of lost data due to equipment failure and storage of backed-up files. (CII.5e)
- I: Evidence is provided validating periodic review and updating of the record format used. (CII.5f)
- I & O: Managers/staff describe and demonstrate compliance with policy and procedure governing the coordination, transport, and security of information shared with and between alternate sites. Staff describe the type of information that is maintained and the procedures for coordination, communication, exchange, and retrieval of required information with the parent organization. (CII.5g)

Note: The Medicare Certified home health agency must comply with CFR 484.10, 484.11, 484.14, 484.18(c), 484.48, 484.48(b), 484.52(b).. See Appendix I HH for a full text of the regulations and a cross-walk.

Note: The Medicare Certified hospice organization must comply with CFR 418.74, 418.74(a,b). See Appendix IH for a full text of the regulations and a crosswalk.

- CII.5 Client records, maintained for each client or client group, are utilized as a tool for coordination of services, as a legal document that is descriptive of care and services provided, and as a resource document for billing and reimbursement.
 - CII.5a All protected health information or client records, hardcopy or automated, are kept confidential and are safeguarded against loss or unauthorized use in accordance with organizational policy and local, state or federal regulations.
 - CII.5b Clients have access to their records and are informed of the process.
 - CII.5c The client record documentation provides client information specific to care and services/products provided, current client status, and progress toward goals and outcomes of care.
 - CII.5d Entries to client record documentation is made only by authorized staff and in accordance with organizational policy and procedure.
 - CII.5e Automated client record systems ensure consistent and ongoing security and protection of data.
 - CII.5f The format for maintenance of client records is reviewed and updated as necessary.
 - CII.5g Organizations with alternate sites ensure consistent documentation, communication, coordination, and retrieval of significant administrative and client/family information.

- **D DOCUMENTATION**
- I INTERVIEW
- O OBSERVATION
- S SURVEY

CII.6

- D: Data reflect measurement of quality of services outcomes. (CII.6a)
- I: Performance improvement manager describes rationale for the performance improvement process and the definition of specific client/service outcomes. (CII.6b,d,e)
- D: A structured framework exists. (CII.6c)
- D: A client satisfaction survey for the current year is available for review and includes, at a minimum, client satisfaction with care and services provided and satisfaction with providers of care. (CII.6f)
- I: The organization describes the mechanism for monitoring client satisfaction. (CII.6f)
- D: Evidence exists of utilization of performance improvement findings to resolve problems and improve quality of service/products. (CII.6g)
- D: Organizational committees and governing body minutes document reporting of trends of performance improvement findings. (CII.6h)
- Note: The Medicare Certified home health agency must comply with CFR 484.52, 484.52(a). See Appendix I HH for a full text of the regulations and a cross-walk.
- Note: The Medicare Certified hospice organization must comply with CFR 418.66, 418.66(a, b, c). See Appendix IH for a full text of the regulations and a crosswalk.

- CII.6 A comprehensive Performance Improvement process integrates the organization's mission and promotes an organizational wide approach that selects, reviews, and analyzes outcomes specific to organizational needs and the scope of services and products.
 - CII.6a Quality is defined and measured in terms of client/service outcomes.
 - CII.6b Specific outcomes are targeted for improvement or replication.
 - CII.6c The organization develops a structured framework for the investigation of target outcomes.
 - CII.6d The organization identifies outcomes to benchmark by utilizing internal standards, processes and protocols; practice or service guidelines; industry research and/or best practices.
 - CII.6e The organization continually evaluates progress toward outcomes and identifies new areas to improve or replicate as indicated by results of data analysis.
 - CII.6f A process for monitoring and measuring the satisfaction levels of clients is conducted at least annually.
 - CII.6g Performance Improvement findings are used to resolve identified problems, improve quality of services and products, and are incorporated into program planning, modification and /or enhancement.
 - CII.6h Trends of Performance Improvement findings are reported to appropriate organizational committees and the governing body.

- **D DOCUMENTATION**
- I INTERVIEW
- O OBSERVATION
- S SURVEY '

CII.7

- D: Personnel records include evidence of adherence to regulatory requirements of Federal OSHA and CDC. (CII.7a)
- D: Written plans define parameters for exposure control, adherence to standard precautions, adherence to work practice controls, HBV prophylaxis and TB exposure control. (CII.7b)
- D: Potential for employee exposure is determined by job classification, which defines the potential for risk and includes: (CII.7c)
 - a) Definition of types of tasks and/or procedures that place an employee at risk for exposure.
 - b) Description of job classifications in which all employees have the potential for occupational exposure.
 - c) Description of job classifications in which employees have the potential for occasional exposure.
 - d) Description of job classifications in which employees have no risk for occupationally related exposure.
- O: Staff demonstrate adherence to standard precautions as determined by organizational policy: (CII.7d)
 - a) Use of gloves
 - b) Use of and accessibility to masks and protective eyewear
 - c) Use of protective gowns and aprons
 - d) Hand hygiene/hand washing techniques including the use of chemical substances
 - e) Techniques for minimizing needle sticks
 - f) Use of puncture resistant sharps containers
 - g) Proper transportation and storage of sharps
 - h) Disposal of contaminated supplies and equipment on site
- S: Random sample of employee records provides evidence of compliance with Hepatitis B (HBV) prophylaxis program. (CII.7f)
- I: Designated person describes procedures followed to ensure compliance with investigative requirements and protection of the rights of the employee who has experienced an occupational exposure. (CII.7f)
- D: Education and training records document compliance with training requirements. (CII.7g)
- Note: The Medicare Certified home health agency must comply with CFR 484.12(c). See Appendix I HH for a full text of the regulations and a cross-walk.
- Note: The Medicare Certified hospice organization must comply with CFR 418.50(b), 418.100 (c), 418.100(i). See Appendix IH for a full text of the regulations and a crosswalk.

- CII.7 The health and safety of employees and clients is promoted and enhanced through education, current application of infection control practices and implementation of appropriate safety measures.
 - CII.7a Adherence to State and/or Federal Occupational Health and Safety Administration (OSHA) and Centers for Disease Control & Prevention (CDC) requirements as applicable that address the health and safety of employees and clients and their protection from blood borne pathogens are validated.
 - CII.7b The organization implements its written Exposure Control Plan.
 - CII.7c The potential for occupational exposure is determined for all job classifications in accordance with state, federal and Occupational Health and Safety Administration (OSHA) mandate.
 - CII.7d Adherence to the use of Standard Precautions by job classification is documented.
 - CII.7e Adherence to work practice and engineering controls is evident in practice.
 - 1) Physical work sites are maintained in a clean and sanitary condition
 - 2) Use of disinfectant solutions
 - 3) Handling, transporting, storage and processing of soiled/contaminated materials, supplies and equipment
 - 4) Use of non-leak infectious waste containers as applicable
 - 5) Identification and labeling of infectious waste as applicable
 - CII.7f Employer and employee responsibilities relating to Hepatitis B prophylaxis (HBV) are defined in writing and include:
 - 1) HBV vaccination and post exposure follow up program
 - 2) Employer/employee responsibilities
 - 3) Declination of HBV statement is signed by employees as applicable and filed in personnel health records
 - 4) Complete and detailed documentation of all exposure events
 - 5) Confidential records are maintained on HBV vaccination and post exposure follow up
 - CII.7g Education and training programs ensure that new employee orientation addresses all aspects of the Exposure Control Plan and that annual training is mandated for all exposure prone employees based on applicable job classification.

- **D DOCUMENTATION**
- I INTERVIEW
- O OBSERVATION
- S SURVEY

CII.7 (Continued)

- D: Occupational exposure information is maintained in confidential records that are retained for the duration of employment plus thirty (30) years. (CII.7h)
- I & O: Clinical, technical and support staff describe potential hazards in the home setting identified during the assessment of the client's living environment. (CII.7k)
- D & I: Evidence exists that the organization monitors and reports information related to adverse events.

Adverse events include but are not limited to:

- provision of care errors
- unusual occurrences
- vehicular crashes
- · other types of accidents or injury
- safety hazards

Serious Adverse Events include but are not limited to:

- unexpected death not resulting from the client's medical condition
- loss of body part
- permanent or partial loss of body function
- blindness

Reports document data on adverse events that predispose the organization to real or potential liability.

- Data are collected within 30 days of an event
- Data are analyzed within 60 days of the event to determine underlying factors leading to the adverse event
- Performance Improvement processes, as applicable, include evidence of organizational changes subsequent to an adverse event

(CII.71)

- D: Medical Device Act reports, as applicable, are on file in the organization and include validation of submission to the FDA. (CII.7m)
- I & O: Staff demonstrate knowledge of and compliance with the organizational infection control practices and procedures . (CII.7n)

- CII.7h The organization demonstrates compliance with its Occupational Exposure Control policies, plan and procedures.
 - 1) HBV is provided at no cost to all employees, potentially subject to occupational exposure, within ten (10) working days of assignments
 - 2) Provision of personal protective equipment as appropriate to all employees with the potential for an occupational exposure as determined by their job classification
 - 3) A confidential medical evaluation and follow-up care is offered to employees who experience an occupational exposure:
 - (a) Counseling
 - (b) Testing of source individual if allowable under local and/or state law
 - (c) Blood testing of the exposed employee with written consent, if medically indicated
 - 4) Accurate, confidential, and timely documentation of:
 - (a) Circumstances leading to exposure
 - (b) Routes of exposure
 - (c) Medical follow-up
 - (d) Opportunity for counseling
 - (e) Other related interventions as indicated and necessary
- CII.7i The organization demonstrates compliance with its TB Exposure Control Plan.
- CII.7j The organization demonstrates compliance with its safety program to monitor environmental conditions for identifying potential hazards/risks.
- CII.7k A routine assessment is made of the client's living environment to identify and evaluate potential safety hazards related to the physical space as applicable.
- CII.71 A system is in place for monitoring and reporting information related to adverse events that endanger the health and safety of clients and/or employees and pre-dispose the organization to real or potential liability.
 - 1) Adverse Events and Serious Adverse Events are defined in organizational policy
 - 2) Data for all events is collected, analyzed tracked and trended as a part of risk management
 - 3) Corrective actions are implemented and evaluated as indicated and necessary
 - 4) Adverse event reports detail each episode and are distributed to advisory boards and accrediting bodies, as applicable
- CII.7m The organization demonstrates compliance with its policy and procedure for the Medical Device Act (MDA).
- CII.7n The organization demonstrates compliance with its Infection Control policies and procedures.

- **D DOCUMENTATION**
- I INTERVIEW
- O OBSERVATION
- S SURVEY

CII.8

- D: Examples of complaint documentation logs. (CII.8a)
- D: Formal documentation of investigative findings and reports as applicable. (CII.8a)
- D: Resolution information is documented as communicated to the complainant. The communication to complainant may be in writing or by telephone. (CII.8b)
- I: Staff describes an understanding of the complaint process. (CII.8c)

Note: The Medicare Certified home health agency must comply with CFR 484.10(b). See Appendix I HH for a full text of the regulations and a cross-walk.

- Cl1.8 Client/ family complaints/concerns are responded to and resolved in a timely manner.
 - CII.8a The complaint process includes intake, investigation, and corrective action as applicable, complaint resolution, written reports, organizational trending and follow-up.
 - CII.8b Resolution/outcome information is communicated to the complainant.
 - CII.8c Staff are aware of organizational mechanisms for receiving and resolving complaints.

CIII.

THE ORGANIZATION HAS ADEQUATE HUMAN, FINANCIAL AND PHYSICAL RESOURCES WHICH ARE EFFECTIVELY ORGANIZED TO ACCOMPLISH ITS STATED MISSION/PURPOSE

- **D DOCUMENTATION**
- I INTERVIEW
- O OBSERVATION
- S SURVEY

CIII.1

- D: Policy, procedure and recruitment documents support a nondiscriminatory approach to hiring. (CIII.1a)
- I&O: Interviews with staff and observation of client practice/service validate adherence to discipline specific practice standards and to regulatory guidelines and requirements specific to respective areas of responsibility. (CIII.1b)
- I: Staff confirm clear understanding of responsibilities and lines of authority. (CIII.1c)
- I: Management explains turnover rate variances as applicable, and describes impact on recruitment and retention activities. (CIII.1d)
- D: Employee records validate the opportunity for a formal exit interview for terminating employees in accordance with organizational policy and procedure. (CIII.1e)
- I: Employees validate receipt of conditions of employment and describe the process for obtaining personnel related information. (CIII.1f)
- D: Employee files are complete and current and include documents specific to CIII.1g. Evidence of verification of education/training may include copies of diplomas, transcripts or telephone validation.
- O: Specified personnel documents are secured in accordance with organizational policy. (CIII.1h)
- Note: The Medicare Certified home health agency must comply with CFR 484.12(c), 484.14(c,e), 484.30(a), 484.32, 484.32(a), 484.34, 484.36(b). See Appendix I HH for a full text of the regulations and a cross-walk.
- Note: The Medicare Certified hospice organization must comply with CFR 418.64, 418.70(a,b). See Appendix IH for a full text of the regulations and a crosswalk.

- CIII.1 The organization has adequate and appropriate human resources to meet caseload and workload demands.
 - CIII.1a A non-discriminatory recruitment and selection process, as defined in policy and procedure, is adhered to.
 - CIII.1b Personnel are employed and assigned responsibilities commensurate with their education and experience.
 - CIII.1c Job Descriptions for each employee category delineate lines of authority and reporting responsibilities, duties to be performed, and educational and experiential qualifications specific to the position.
 - CIII.1d Employee turnover rates are monitored tracked and trended, as applicable.
 - CIII.1e The opportunity for exit conferences are offered to terminating employees, are documented and trended, as applicable.
 - CIII.1f Personnel policies/conditions of employment are provided to employees at the time of hire and thereafter as updates/revisions are needed.
 - CIII.1g Evidence of the following employee information is maintained in accordance with organizational policy and regulatory guidelines.
 - 1) Individual job qualifications
 - 2) Verification of education/training
 - 3) Certification for specialty areas of practice as applicable
 - 4) Statement of formal training for non-professionals
 - 5) Two (2) reference checks
 - 6) Pre-employment interview(s)
 - 7) Current license or certification as applicable
 - 8) Validation of competency skills testing as applicable
 - (a) Time of hire
 - (b) Annual
 - 9) Validation of performance evaluation at end of probation and annually
 - 10) Validation of malpractice coverage for independent contractors
 - 11) Validation of completion of the orientation process (new and reassigned personnel)
 - 12) Validation of signed and dated confidentiality statements
 - 13) Validation of in-service/continuing education participation as applicable
 - 14) Validation of exit interview as applicable
 - 15) Miscellaneous items per state, federal or organizational requirements
 - 16) Criminal background checks in accordance with organizational policy and procedure and local and/or state law
 - 17) Immigration and naturalization statement (I-9)
 - CIII.1h Specified personnel documents and employee health reports may be retained in separate files per organization policy.

D - DOCUMENTATION

I - INTERVIEW

O - OBSERVATION

S - SURVEY

CIII.1 (Continued)

- D: Annual evaluation form addresses elements of CIII.1i as applicable to the job category.
- I: Sample of employee and supervisory staff personnel records confirms adherence to the annual evaluation process. (CIII.1i, 1j)
- D: A written plan details the orientation of new personnel and for personnel assigned to a new job classification. Components of the orientation plan may include mission and purpose of the organization, table of organization, lines of authority and responsibility, hours of work, job-related responsibilities, and personnel policies. (CIII.1k)
- I: Recent hires describe their orientation as comprehensive and pertinent to meeting job responsibilities. (CIII.1k)
- I: Staff assigned to a new job classification describe their orientation to the new responsibilities. (CIII.1k)
- I: Staff validate receiving applicable hours of in-service programming and describe the types of experiences available to them. (CIII.11)
- O: Federally required in-services include OSHA mandated. Staff Development opportunities may include: independent study, satellite learning, specialized conferences, formal courses of study and mentoring. (CIII.11)
- D & I: Policy and managers describe the process for assuring that personnel are identified. Service contracts with organizations detail the process that the sub-contract organization will assure sub-contract organization identification of staff. (CIII.1m)

- CIII.1i An annual written performance evaluation process is completed on all employees by the respective supervisor and includes:
 - 1) Supervisor assessment of employee performance in accordance with established criteria (Job Description)
 - 2) Achievement of previously established goals
 - 3) On site evaluation reports/competency testing for clinical/field/service staff
 - 4) A signed, dated validation of the evaluation process by the employee and employer representative
- CIII.1j An annual performance evaluation process provides an opportunity for active participation by employees through:
 - 1) Employee development planning/new goal setting
 - 2) Employee response to evaluation
- CIII.1k A written plan details the orientation process for all new and reassigned employees which addresses applicable elements pertinent to each job classification.
- CIII.11 The organization shall provide in-service and staff development as needed and as required by local, state and federal regulation and national and/or professional standards as applicable.
- CIII.1m Personnel are provided with identification badges or are identified as working for the organization.

- **D DOCUMENTATION**
- I INTERVIEW
- O OBSERVATION
- S SURVEY

CIII.2

- D: A review of a randomized sample of written contracts for the provision of care, services and/or products validates adherence to CIII.2, a, b.
- I: Contract manager or other designated party describes the ongoing management and control of contractual agreements. (CIII.2a)

Note: The Medicare Certified home health agency must comply with CFR 484.14, 484.14(f, h), 484.36(d). See Appendix I HH for a full text of the regulations and a cross-walk.

Note: The Medicare Certified hospice organization must comply with CFR 418.56, 418.56(b,c,d,e), 418.80). See Appendix IH for a full text of the regulations and a crosswalk.

- CIII.2 Formal written contracts, executed by the primary organization with other professionals and entities for the provision of care, services, and products to clients of the primary organization, detail specific responsibilities of the parties involved.
 - CIII.2a Written service contracts with individuals and/or other entities are signed and dated by authorized principals of each party and are reviewed annually.
 - CIII.2b The executed document stipulates the terms of the contract which include:
 - 1) Specific services/products to be provided
 - 2) Contractor is required to adhere to applicable primary organization's policies and procedures
 - 3) Assurance by the contractor of the education, training, qualifications and identification of personnel designated to provide care, services, and products
 - 4) Mechanisms for the contractor parties to participate in Performance Improvement activities as applicable
 - 5) Procedures for the documentation and submission of documented notes that verify the provision of services/products in accordance with the written service contract
 - 6) Procedures for the submission of bills and related information and reimbursement for care, services and products provided
 - 7) Effective dates of the contract including terms of renewal and/or termination

- **D DOCUMENTATION**
- I INTERVIEW
- O OBSERVATION
- S SURVEY

CIII.3

- D: Organizational policy and procedure detail the fiscal activities and responsibilities of the organization. (CIII.3a)
- I: The chief financial manager confirms credentials and experience background for the responsibilities assigned and describes the budget planning process. (CIII.3b)
- D: Governing Body minutes confirm approval of budgets and other financial agenda items referred to the Governing Body. (CIII.3c)
- D: The organization has a current operating budget and capital expenditure plan. (CIII.3d)
- D: Financial, statistical and productivity reports are used to facilitate oversight of the organization's operations. (CIII.3e)
- I: The chief financial manager describes the use of financial, statistical or productivity reports. (CIII.3e)
- I: The chief financial manager validates the adequacy of insurance coverage. (CIII.3f)
- D: Review of annual financial review validates that the review was conducted by an organization external to the organization within the most recent twelve month period. (CIII.3g)

Note: The Medicare Certified home health agency must comply with CFR 484.14(i). See Appendix I HH for a full text of the regulations and a cross-walk.

Note: The Medicare Certified hospice organization must comply with CFR 418.52, 418.56(d). See Appendix IH for a full text of the regulations and a crosswalk.

- CIII.3 The organization's sources of financial support are managed and monitored on an ongoing basis to ensure the availability of adequate funding.
 - CIII.3a Financial policies and procedures govern the fiscal activities of the organization.
 - CIII.3b The chief financial manager has the appropriate qualifications, credentials and expertise to oversee, manage, and direct the fiscal operations of the organization.
 - CIII.3c Major participants in developing and monitoring the budgetary process include the governing body, the chief executive, the chief financial manager, program directors and other designated staff as appropriate.
 - CIII.3d The operating budget and operating capital expenditure plan is developed using methodologies commensurate with the scope and complexity of the organization's services, programs, and products and is used to forecast financial and operating successes and challenges.
 - CIII.3e Financial management tools are used to provide operational feedback to administrative and management personnel, financial committees and the governing body.
 - CIII.3f Adequate insurance coverage is maintained.
 - CIII.3g An annual external review is required and conducted.

- **D DOCUMENTATION**
- I INTERVIEW
- O OBSERVATION
- S SURVEY

CIII.4

- D: Financial reports detail information used to measure operational performance. (CIII.4a, b)
- I: The chief financial manager or other designated party describes the effectiveness of the financial management information systems, the types of reports generated and their use, and internal financial controls (CIII.4a, b, c)
- D: Organizational financial procedures used for internal control may include segregation of duties, reconciliation of control accounts, approval levels for disbursements and adjustments, collection of accounts receivable, budgeting, receipt of funds, disbursement of funds, cash and asset account reconciliation and cash management. (CIII.4c)
- I: Financial /billing staff confirms timely billing procedures, ongoing monitoring of accounts receivable, implementation of collection efforts as appropriate, and adherence to accounts receivable guidelines. (CIII.4d)
- D: Financial reports include payroll and vendor disbursements in accordance with CIII.4e.

Note: The Medicare Certified home health agency must comply with CFR 484.14(i). See Appendix I HH for a full text of the regulations and a cross-walk.

- CIII.4 A financial management information system is used to document and monitor all financial components and provide appropriate and timely reports to all levels within the organization.
 - CIII.4a The financial reporting system produces detailed data regarding actual transactions specific to care, services and products provided by each program including site/ location activity.
 - CIII.4b Periodic financial statements contain key indicators and show a reasonable match between revenue and expense line items.
 - CIII.4c Internal financial controls are in effect.
 - 1) Internal audit procedures and annual review of budget are conducted.
 - 2) Adherence to organizational financial policies and procedures is monitored.
 - CIII.4d Reimbursable services are billed on a timely basis in accordance with designated fee structures and are monitored, tracked and aged.
 - CIII.4e Payroll and vendor disbursements are recorded and processed in a structured and timely manner.

- **D DOCUMENTATION**
- I INTERVIEW
- O OBSERVATION
- S SURVEY

CIII.5

- D: Applicable statements indicating compliance with OSHA, CDC, ADA, are available and may include:
 - 1) Fire drill and health inspection reports indicate compliance.
 - 2) Certificates of occupancy are posted in accordance with local requirements.
 - 3) Fire and emergency exits clearly detail areas of entrance and egress.
 - 4) Hazardous area access is controlled.
 - 5) Hazardous chemicals and solutions are properly labeled and kept in locked storage.
 - 6) Adequate space and privacy is provided to employees and clients receiving services.
 - 7) Facilities are barrier free and/or special arrangements are made to provide access as indicated and necessary.
 - 8) Safety and security procedures for employees are implemented as necessary.

(CIII.5a)

- O: Tour of facility validates compliance with OSHA, CDC, and ADA guidelines and applicable local requirements. (CIII.5a)
- Note: The Medicare Certified home health agency must comply with CFR 484.12(a). See Appendix I HH for a full text of the regulations and a cross-walk.
- Note: The Medicare Certified hospice organization must comply with CFR 418.56(c), 418.100(c). See Appendix IH for a full text of the regulations and a crosswalk.

CIII.5 Physical facilities are adequate to support the operations.

CIII.5a Physical facilities meet the OSHA (Federal/State), CDC, ADA and/or State or Local regulations for environmental protection and safety of employees and recipients of service.

- **D DOCUMENTATION**
- I INTERVIEW
- O OBSERVATION
- S SURVEY

CIII.6

D&I: MIS manager or other designated party explains and demonstrates how data are collected, processed and secured on and off site. (CIII.6a)

I: Management describe how information system is used to ensure organizational accountability. (CIII.6)

CIII.6 A management information system is utilized to ensure accountability at all levels of the organization.

CIII.6a A manual or automated system utilizes established standards and defined data elements for the collection and processing of information.

CIV.

CIV.

THE ORGANIZATION IS POSITIONED FOR LONG TERM VIABILITY

- **D DOCUMENTATION**
- I INTERVIEW
- O OBSERVATION
- S SURVEY

CIV.1

- I: Management and staff describe the planning process. (CIV.1a)
- I&O&D: The assessment of the strengths, weaknesses, opportunities and threats may include the following components:
 - 1) Assess and analyze service area demographics.
 - 2) Maintain current knowledge of organization's market penetration.
 - 3) Identify new and/or changing consumer and community needs.
 - 4) Collect data and information for analysis.
 - 5) Garner input from all levels of staff.
 - 6) Determine organizational priorities. (CIV.1b)
- I: The CEO and/or governing body representative describes the long term vision and goals for the organization. (CIV.1b)

- CIV.1 Strategic planning reflects the organizational mission and includes a comprehensive evaluation of both internal and external environments.
 - CIV.1a Current budgetary, business and marketing activities are integrated into the process.
 - CIV.1b An assessment of the organization's strengths, weaknesses, opportunities and threats is conducted on a periodic basis.

- **D DOCUMENTATION**
- I INTERVIEW
- O OBSERVATION
- S SURVEY

CIV.2

- D: The organization provides evidence that a current annual evaluation was conducted timely and in accordance with its organizational policies and process.(CIV.2a)
- D: The annual evaluation report validates the inclusion of service/product, risk management, human resources and financial and operational components in the evaluation process. (CIV.2b)
- I: Administrative/management personnel describe how the complexity of the organization relates to data collection and utilization. (CIV.2b)
- D&I: Minutes and interview confirm that the annual evaluation report was presented to the appropriate advisory and governing bodies. (CIV.2d)

Note: The Medicare Certified home health agency must comply with CFR 484.16. 484.16(a), 484.52, 484.52(a). See Appendix I HH for a full text of the regulations and a cross-walk.

Note: The Medicare Certified hospice organization must comply with CFR 418.66. See Appendix IH for a full text of the regulations and a crosswalk.

CIV. 2 An Annual evaluation of the organization provides the basis for future planning.

- CIV.2a Organizational policies drive the process for the annual program evaluation by an authorized group and identify the components to be evaluated.
- CIV.2b The complexity of the organization and the scope of care, services, and products provided define the parameters for data collection and utilization and includes service/product, risk management, human resources and financial data.
- CIV.2c Variances from usual and expected patterns of performance are analyzed and explained.
- CIV.2d The Annual Evaluation Report is presented to advisory and governing bodies as appropriate.
- CIV.2e The Annual Evaluation Report is retained as an administrative record.



CORE

SELF STUDY

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INTRODUCTION TO CORE SELF STUDY

The Community Health Accreditation Program, Inc. (CHAP) accreditation process is comprised of five steps:

- Submission of an application and application fee
- Submission of a signed contract accompanied by a pre-determined initial fee
- Submission of a completed Self- Study
- Comprehensive Site Visit by a team of professionals, the number of which is determined based on the size of the organization and complexity of services provided.
- Submission of the Site Visit Report to the Board of Review for Review and Determination of Accreditation Status.

The Self-Study process is completed by the organization seeking CHAP Accreditation:

2)

- Prior to the initial site visit
- Prior to the first visit of a new contract cycle

What is the Self-Study?

The Self-Study is a dynamic tool, used by organizations seeking CHAP Accreditation, which assists the organization in preparing for the on-site accreditation visit. The process involves a comprehensive internal self-assessment of the organization's:

- Structure and Function
- Quality of Services and Products provided
- Resources: Human, Financial and Physical
- Long Term Viability

Suggestions for the Completion of the Self-Study

programs and/or departments. Selection of a chairperson, who assumes oversight responsibilities for the group, will assure adherence Standards in order to avoid duplicative responses. CHAP also recommends that the Standards of Excellence and Evidence Guidelines to established time frames and keep the committee focused on achieving a positive accreditation outcome. CHAP recommends that Sections I, II, III, and IV of the CORE Self-Study be completed prior to completing the companion sections in the Service-Specific CHAP recommends that a coordinating committee be appointed, comprised of representatives from each of the organization's be utilized with the self-study as the organization assesses itself for compliance with the CHAP Standards.

Reaching group consensus on implementing a working agenda

- Strategies for completion of the document
- Assignment of responsible parties
- Estimated time frames for completion of various components of the process
- Processes for monitoring specific activities
 - Meeting schedules and progress reports
- Projected date for the submission of the completed Self-Study document
- Retrenchment as necessary and indicated

Directions for Completion of the CORE Self-Study Document

The CORE Standards and Self Study are used in concert with the applicable service specific standards and self-study.

Complete the following documents of the Self-Study:

- 1) Contact Information Sheet
 - Organizational Data Sheet 2) Organizational Data Sheet3) Organizational Questions4) Self-Study Spreadsheet

Core

The eight (8) column format is defined as follows from left to right:

Column 1 CHAP Standards Alpha-numeric identifiers

Column 2 A description of the following:

Underlying Principles

Standard Statements

Criterion Statements

Elements of the Criterion (numeric identifier i.e., 1)

Sub elements of a Criterion (identified by use of an alpha letter i.e., a)

Columns 3&4 Identification of documents/information/activities that are either "In Place" or "Not In Place"

3 = ``Yes'' If in place, check appropriate box

• 4 = "No" If not in place, check appropriate box

"N/A" - Used to indicate that a Standard, Criterion, Element or Sub-element is not applicable to the organization completing the Self-Study. If N/A, check appropriate box Column 5

attachment to the Self-Study. That designation will be included on the Self-Study by CHAP prior to being sent "A/R" Indicates those standards/criterion which must have a substantiating document submitted as an to your organization Column 6

"A/O" - Attachment Optional. An attachment that may be designated by CHAP or the organization seeking accreditation Column 7

Comment space for notations or points of clarification by the organization seeking accreditation by CHAP Column 8

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Submission of Self-Study:

Submit self-study and required attachments to CHAP Site Visitor Coordinator, CHAP, Inc., 39 Broadway, Suite 710, New York, New York, 10006. Refer to the original contract letter for specific number of self-studies required to be submitted to CHAP.

In addition to the self-study required attachments, submit one (1) copy each of the following:

- 1. Copy of the structured framework for the investigation of target outcomes.
- 2. Copy of job description for each key position category
 - 3. Template for Service Contracts (if available)4. Financial Statements (audited/reviewed/internal)
- past three (3) years. Multi-unit organizations should send audited consolidated statements of the Corporate/ Balance sheet; Statement of Cash Flows; Income Statements and/or supplementary spreadsheets for the Parent organization.

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CORE Self Study

Contact Information

For:
Name of Organization
Location:
Contact:
Telephone:
E-mail:
Submission Date: Note: This should be the first page of your Self Study.

Mail to: Site Visit Coordinator CHAP, Inc.
39 Broadway, Suite 710
New York, NY 10006

ORGANIZATIONAL DATA SHEET CORE

<u>Administrative Profile</u>
(Only include positions not included in service-specific organizational data sheets)

	udgeted*	udgeted* Current FTEs	<u>FTE Positions Budgeted*</u>	Executive Staff:	Supervisory Staff:	Support Staff (office/clerical):	Other (Specify)	Other (Specify)	Other (Specify)
Current FTEs Vacant Positions	Vacant Positions		Contract Staff						

* FTE = Full time equivalent (40 hour week = 2,080 hours per year)

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ORGANIZATIONAL DATA SHEET CORE

Turnover Rates for Past Fiscal Year:

Category of Positions	# of	Percent
	Individuals	(%)
Exec/Admin/Management staff		
Supervisory staff		
Direct care/service staff		
Professional		
Paraprofessional		
Technical		
Support staff (office/clerical)		•
Other (specify)		
TOTAL		

Revenue/Expense: (Last fiscal year)

69 Total annual revenue: Total annual expense:

Insurance coverage maintained:

↔ ↔ Directors & Officers liability: Property & Casualty: General liability:

Workers Comp: Other (Specify) Malpractice:

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Core Self Study CHAP, Inc.

ORGANIZATIONAL DATA SHEET (cont d.)
CORE
Service Data
Dates of last fiscal year:
Total unduplicated clients in last fiscal year:
Total volume services in last fiscal year:

Service Description

Organization:
rovided by Or
s/Products P
of Services/
Types of

•			
	ea:		
	Description of Geographic Service Area:		

Service Volume Change Over Previous Three (3) Year Period:

Core Self Study CHAP, Inc.

ORGANIZATIONAL QUESTIONS

CI. STRUCTURE & FUNCTION OF THE ORGANIZATION

1. What is the organization's Governing Body? Describe the structure and function.

What responsibilities and activities are delegated to the Chief Executive by the Governing Body? ri What mechanisms are employed to keep the Governing Body informed of organizational issues? 4

CI. (cont'd.)

i. How does the organization develop and implement policies?

What significant changes have occurred in the organization during the past two years? Please describe. Ś

CII. QUALITY OF SERVICES & PRODUCTS PROVIDED

How does the organization use the results of performance improvement activities to make changes for all Describe for all programs/services seeking accreditation. programs/services?

CIII. ADEQUATE RESOURCES

How does the organization assess its need for adequate staff, physical space and financial resources for all Describe for all programs/services seeking accreditation. programs/services? -

CIV. LONG TERM VIABILITY

1. Describe the challenges facing the organization's long term viability.

Describe how the organization is positioning itself to ensure future viability. 7

	Description	IN PLACE	二	\dashv	Comments
		YES NO N	WA AIR	AIG	
000	Published Mission schement identifies sommitteet to quality & consumerare ads		×		
Cl.1a	Programs & Services reflect organization's written mission				
Cl.1b	Mission statement is reviewed/approved by GB every 36 months				
600	State in which contains the profits of the Market Contains the Contains of the	,			102
CI.2a	Legal authority to operate & in compliance with local, state, and federal regulations				
CL2b	Governance Structure is defined in legal documents specific to the organization.				
CI 2c	An identified governing body:				Þ
	1) Assumes full legal authority/responsibility/accountability for organizational performance				
	2) Appoints a qualified administrator				
	3) Designates advisory group membership as applicable				
Cl.2d	GB membership comprised of individuals with relevant expertise, business acumen, and professional relationships specific to the organization's stated mission		×		
Cl.2e	GB members are oriented to the organization & are knowledgeable &responsive to key issues affecting the organization				
CLZf	GB carries out responsibilities specific to the organization including:				
	1) Establishing policies consistent with organizational mission				
	2) Approving new/revised P&P's as indicated & necessary				
	3) Holding management accountable for the organization's solvency & finances				
	4) Approving budgets & capital expenditures				
	5) Selecting & evaluating the chief administrator				
	6) Evaluating organizational performance				
	7) Developing & approving strategic plan				
	B) Periodically reviewing legal & business documents, at least every 36 months (Article of Incorporation, By-laws, Legal Agreements)			_	
Cl.2g	GB members & executive staff provide annual written disclosure of all professional &for personal relationships or interests, direct or indirect, that might represent a conflict of interest. Signed annual disclosure statements are on file in the office.				
CLZh	The GB complies with organizational by-Jaws or other legal documents.				
CLZi	Accurate, complete, & signed minutes are kept of all official meetings of the GB				
	1) Actions taken are documented.		-		
	2) Minutes are distributed in accordance with organizational policy				
	3) Minutes are retained at least 5 years or consistent with state regulations.				
603	interorganizationalmistrate clearly defined				
Cl.3a	Current organizational chart delineates lines of authority & accountability of all personnel		×		
Cl.3b	Organizational chart is reviewed and changed as needed				
Cl.3c	Personnel understand & use appropriate lines of authority as outlined in the organizational chart.				

	Description	IN PLACE			Comments
		YES NO	N.A	AIR AID	
9	Authority & responsibility for overall deministration & management (sives field in fulfill) in dividuals \$7.				
Cl.4a					
C.46				×	
Cl.4c	Qualified person is designated in writing to assume administrative responsibility in the absence of chief executive/administrator.			×	
Cl.4d					
	1) Organizing & directing the organization's ongoing operations to assure availability and provision of care & services				
	2) Implementing GB directives & organizational P&P's				
	3) Complying with applicable laws & regulations				
	4) Recruiting, employing & retaining qualified personnel to maintain appropriate staffing levels				
	5) Ensuring adequate staff education				
	6) Completing performance evaluations on subordinate staff in accordance with organizational policy				
ļ	7) Directing/monitoring organizational Performance Improvement activities				
	 B) Managing operations in accordance with established fiscal parameters 				
	9) Planning, developing, Implementing, administering & evaluating programs				
	10) Representing the organization to other groups, organizations & the general public				
	11) Ensuring the accuracy of public information materials				
	12) Informing the GB & staff of current organizational, community & industry trends				
0.55	Organizations (PAT's) ordiocamamphasis conqualty, beint campactice & related friedly to the mission of the organization				
Cl.5a	P&Ps are developed, revised, & reviewed annually to assure currency of information				
Cl.5b	Administrative P&Ps delineate administrative authority, & responsibility for governance, planning, francial control & personnel. Policies include at a minimum:				
	1) Written disclosure of conflict of interest				
	2) Public disclosure of information			×	
	3) Responsibilites of ethical issues review group			×	
	4) Rights & responsibilities of clients			×	
	5) Internal & external compliaint management			×	
	6) Exposure control plan			×	
	7) Formal safety program			×	
	8) Financial policies & procedures			×	
	 Research activities/investigational studies as applicable 				
Cl.5c	Operational P&Ps form the framework for planning, delivery & evaluation of care, & services provided. Policies include at a minimum:				
	1) Non-discrimination statement addressing admission of clients to service				
	2) Defined criteria for acceptance/non-acceptance of clients				
	3) Admission, continuation of service, & discharge				
	4) Standardized assessment process				

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		N DI ACE	Ĺ	Commonte	Г
	nescription				Т
		TES NO	¥	NO.	Т
	5) Referral to other providers of care/services				
	6) Medical orders, verbal orders & physician oversight as applicable				
	7) Emergency Service				
	8) After hours service				
	9) Confidentially of protected health information		×		T
	10) Emergency /disaster preparedness				Γ
	11) Health, safety & security of staff during all hours of work				<u> </u>
	12) Services/products provided directly & under contract				Π
	13) Standards of practice for all disciplines as applicable		×		
	14) Standards of operations for all products as applicable				
	15) infection control		×		
	16) Accepted medical term abbreviations				T
Cl.5d	Personnel policies are developed & revised in response to organizational change & include:				Γ
	1) Candition of employment				Π
	2) Respective obligations between employer & employee				
	3) Non-discrimination information			-	Г
	4) Grievance procedure				Т
	5) Employee orientation		_		Π.,
	6) Employer exit interviews				Γ
	7) Maintenance of health reports & protected employee information				
	8) Employee record confidentiality & record retention				
	9) Recruitment, retention, & performance evaluation of staff				
Cl.5e	A written TB Exposure Control Plan is in compliance with the most current CDC applicable recommendations & requirements for occupational exposure to TB. The plan addresses:		×	`	
	1) Definition of employees at risk of occupational exposure to TB				
	2) Process for identifying suspected or confirmed cases of TB				
	3) Control of employee exposure when a client is suspected or confirmed as having infectious TB				
	4) Education & training to all employees to the hazards of exposure to TB at time of hire & annually thereafter.		_		Π
	5) Pre-employment & subsequent periodic TB screening of employees in accordance with written policy				
	6) Provision of follow-up care to employees exposed to TB				
	7) Provision of follow-up care to employees who convert to active disease				
	8) Provision of appropriate personal protective equipment when caring for a suspected/confirmed TB client				
	9) Provision of work practice oversight to minimize occupational exposure to TB				
	10) Adherence to reporting & record keeping requirements per state/federal law				
Cl.5f	Organizational P&PS address the requirements of the Medical Device Act (MDA) & delineate the mechanisms for reporting incidents which result in serious injury, illness, or death				
	1) Reports are filed with the Federal Drug Administration (FDA) according to regulation		·		
	2) A designated person is responsible for ensuring compliance with reporting requirements				

	Description	IN PLACE			Comments
		YES NO	NVA AJR	γQ	
	3) Criteria for designation of reportable events are defined				
	4) Written protocols for investigation of events are defined				
	5) Investigative activities are initiated on a timely basis				
	6) Accurate documentation of findings include:				
	a) Investigative findings				
	b) Copies of reports sent to manufacturer				
	c) Copies of reports to the FDA				
	7) Retention & retrieval of findings & reports				
	8) In-service education on MDA reporting is provided to staff on an annual basis				
	a) Written curriculum outlines training content				
	b) Records of attendance are maintained				
Cl.5g	Infection Control P&P's detail systems designed to promote the prevention & control of infections, monitor the occurrence of infections & evaluate the effectiveness of infection control practices		×		
	1) Current infection control practices & strategies				
	2) Identification & investigation of breaks in technique				
	3) Sources of infection				
	a) Nosocomial				
	b) Home acquired				
	c) Professional exposure				
	4) Types of infection				
	5) Modes of transission of inction				
	B) Contributing causes of infection				
	7) Data collection, analysis, tracking, & trending of findings				
,	8) Reporting requirements per state & federal regulations				
	g) Documented evidence of in-service education for staff includes:				
	a) Dates & times of programs				
	b) Curriculum outline of training content				
	c) Records of staff attendance				
	10) Cilent/family teaching				
	11) Use of personal protective equipment				
	12) Accepted hand hygiene techniques				
Cl.5h	Administrative, financial, client. & personnel records are secured, retained, & retrievable in accordance with formal record retention policy [hat is in compilance with organizational policy & local/state/federal law		×		
	1) Minutes of all official meetings of GB are retained for at least 5 years				
	2) Client adult records are retained for at least 5 yrs after provision of service				
	3) Client records of minors are retained for at least 7 yrs after age of majority is reached				
	4) Mechanisms for client access & release of client records are defined				

	Description	IN PLACE			Comments
		YES NO	NIA AM	ΥD	
	5) Organization has defined authorization for client record documentation & entry & signature authorization/authentication for automated client record system in accordance with individual state law				
	6) Organization has defined process for maintaining safety & security of client records				
	7) Conflidential records for employees experiencing an occupational exposure are retained for the duration of employment plus 30 yrs				
	B) Annual training records for exposure prone employees are retained for at least 3 yrs				
	9) Client records involved in litigation are retained until after settlement				
CI.51	Staff members have access to P & Ps				
90	information is provided to clients ramilies jointlying the availability of organizational & committy resources to assist in madring plant needs		×		
Cl.6a	Language specific written materials, as necessary & appropriate, are available for distribution to cirents/families				
CI.6b	Interpretive services are provided, as indicated & necessary, to ensure accurate communication between client/family/caregiver & other types of health services personnel				
<u>5</u>	The organizations in issues, clinical, disease prevention & health promotion activities are conducted according to ethical sentials.				
Cl.7a	A group of qualified professionals is designated by the CB to review ethical Issues as they arise				
Cl.7b	Written P&Ps outlines responsibilities of the group & delineales the process for submitting ethical concerns & issues for action		×		
Cl.7c	Meeting minutes clearly document group activities & are referred to the GB for review & final action as indicated & necessary				
88	The organization considers requests for assauch in the sare of community public health as appropriate				
Cl.Ba	A mechanism is in place for reviewing, processing & approving internal & external research proposals				
CI.8b	Organizational P&Ps define parameters for participation in research activities & investigative studies				
	1) Research protocols, as applicable, for internally & externally sponsored activities are on file				
	2) Potential participants are provided written information regarding the nature, process, & benefits of the research outcomes				
	3) Risks associated with the project are clearly defineated				
CI.8c	Organizations participating in research or investigative studies ensure that clients & staff are fully informed				
CI.8d	Formal written consents for participants in research ∨ investigative studies are obtained & retained on file in the organization				
Cl.8e	New knowledge from internal or external research is integrated into practice, as applicable				

	Description	IN PLACE		_	Comments
		YES NO	WA A	AIR AID	
	SSIVAES-IOUVITIVO	Concernication			
10	Mishori crives the actualise of the Organization & ensures public disclosure; climit lights & ethical standards of tue inness & clinical practice:	sannya ana			
CII.1a	a Public disclosure policy defines availability & accessibility of public information & includes:			×	
	1) Ownership Information				
	2) Statement of organization's mission				
	3) Licensure & accreditation status, as applicable				
CII.1b	A written Client Bill of Rights recognizes, protects & promotes the right of each client to be treated by with dignity and respect.			×	
	1) Written P&Ps defines rights & responsibilities of clients				
	2) Clients receive notice of rights prior to receiving pre-planned care				•
	3) Clients are knowledgeable of right to exercise rights at any time				
<u> </u>	4) Distribution of required Information to clients is documented				
	5) The client/client's designated representative is authorized to exercise rights				
	6) Confidentially of client record/data is maintained by the organization				
	7) Access to care/services is based upon non-discrimination				
	B) Clients are informed of right to voice complaints/grievances to the organization regarding insaffined the companies of the companies o				
	9) Receive in writing the telephone numbers of the CHAP hot line, including hours of operation & purpose of the hot line to receive complaints or questions about the organization.				
	10) Clients are informed of right to participate in care/service plan development				
	11) Clients are informed verbally and in writing prior to start of care and as changes occur of billing/tenbursement methodologies, including fees for services/products provided, direct pay resconsibilities. & nofficiation of insurance coverage.			×	
CIL 1c				×	
CII.1d	Reasonable attempt is made & documented to ensure that client & family understand their rights & responsibilities which are reviewed with client not to start of care or at time of initiation of care and periodically reviewed thereafter				
200	Care-seyltes <u>A</u> products-are available to & accessible by the clienticient & normendative	Name (C			
CII 2a	Care, services & products are provided within an established time frame, as specified by organizational policy, organizational standards, medical directives or individual physician orders. Consideration is given to the client &for family needs in scheduling & providing care.			×	
CII.2b	Collaboration & networking with other providers enhance provision of care & services as applicable				-
CII2c	Supervisory & clinical/service staff demonstrate knowledge of organizational P& P for ensuring delivery of care, services, & products to clients.				
	TOTAL STREET	30 28898		×	
CII.3a				×	
CII.3b				×	
CII.3c	3c Staff are knowledgeable of the practices & procedures relative to emergency preparedness responsibilities & emergent events				
611.4	iner & inter organizational coordination is evident in the planning. Implementation monitoring & exclusion of care (& services) recollect.				
CII.4a	Coordination between clinical/service, financial & operational components of the organization to				
ciliz	Clientercods: maintained for each client or client group; are till bertack tool for coordinators of services; as a legal document finalise descriptive or care. A service-sprowted As a a resource document for all ling As immunisement.	4042846C			•.

	Docarintion	IN PLACE	L		Communic
		£ 52	HIA AIR	O.A.	Communico
			—-		
CII.5a	Ali protected health information or client records, hardcopy or automated, are kept confidential and safeguarded against loss or unauthorized use in accordance with organizational policy & local/state/federal regulations				
CII.5b	Clients have access to their records & are informed of the process				
CII.5c	Client record documentation provides client information specific to care & services/products provided, current client status & progress toward goals & outcomes of care				
CII.5d			×		
CII.5e	_				
CII.5f	The format for maintenance of client record is reviewed & updated as necessary				
CII.5g			-		
	ant attack a strick				
CII.6a	Quality is defined and measured in terms of client/service outcomes				
CII.6b	Specific outcomes are targeted for improvement or replication				
CII.6c					
CII.6d	The organization identifies outcomes to benchmark by utilizing internal standards/processes/pro industry research &/or best practices				
CII.6e					
CII.6f			×		
CII.6g	Performance Improvement findings are:				
	1) Used to resolve identified problems				
	2) Used to improve quality of services/products				
	3) Incorporated into program planning/modification/enhancement				
CII.6h	Trends of Performance Improvement findings are reported to appropriate organizational committees (& the GB				
	The haalung, well-being of employees & clients is promoted & enhanced through aducation; current application of infection committing particles & implementation of appropriate safety measures.				
CII.7a	Adherence to regulatory requirements that address the health & safety of employees & clients & their protection from blood borne pathogens is validated				
-	1) State & for Federal OSHA mandates as applicable				
	2) CDC recommendations & guidelines				
CII.7b					
CII.7c	The potential for occupational exposure is determined for all job classifications in accordance with state/federal & Occupational Health & Safety Administration (OSHA) mandate		×		
CII.7d	Adherence to the use of Standard Precautions by Job classification is documented				
CII.7e	Adherence to work practice & engineering controls is evident in practice				
	1) Physical work sites are maintained in clean & sanilary condition				
	2) Use of disinfectant solutions	-			
	3) Handling, transporting, storage & processing of soiled/contaminated materials, supplies & equipment				
	4) Use of non-leak infectious waste containers as applicable				
	5) Identification & labeling of infectious waste as applicable				
CII.71	Employer & employee responsibilities relating to Hepatitis B prophylaxis (HBV) are defined in writing & include:				
	1) HBV vaccination & exposure follow-up program				

	Description	IN PLACE Comments
		YES NO MA AR AD
	2) Employer/employee responsibilities	
	3) Declination of HBV statement is signed by the employees as applicable, & filed in personnel health records	
	4) Complete & detailed documentation of all exposure events	
	5) Confidential records are maintained on HBV vaccination & post exposure follow-up	
CII.7g	Education & training programs ensure that:	
	1) New employee orientation addresses all aspects of the Exposure Control Plan	
	2) Annual training is mandated for all exposure prone employees based on applicable job classification	
CII.7h	The organization demonstrates compliance its Occupational Exposure Control policies, plan & procedures	
	1) HBV is provided at no cost to all employees, potentially subject to occupational exposure, within 10 working days of assignment	
	 Provision of personal protective equipment as appropriate to all employees with the potential for an occupational exposure as determined by their job classification 	
	3) A confidential medical evaluation & follow up care is offered to employees who experience an occupational exposure:	
	a) Counseling	
	b) Testing of source individual if allowable under local and/or state law	
	c) Blood testing of exposed employee with written consent, if medically indicated	
	4) Accurate, confidential, & timely documentation of:	
	a) Circumstances leading to exposure	
	b) Routes of exposure	
	c) Medical follow-up	
	d) Opportunity for counseling	
	e) Other related interventions as Indicated & necessary	
CII.71		
CII.7]	1	×
CII.7k	A routine assessment is made of the client's fiving environment to identify & evaluate potential as applicable	
CII.71	-	×
	1) Adverse Events & Serious Adverse Events are defined in organizational policy	
	2) Data is collected for all events, analyzed/tracked/ trended as a part of risk management	
	3) Corrective actions are implemented & evaluated as indicated & necessary	
	4) Adverse event reports detail each episode & are distributed to advisory boards & accrediting bodies as applicable	
CII.7m	The organization demonstrates compliance with its P & Ps for the Medical Device Act (MDA)	
CII.7n	. The organization demonstrates compliance with its infection control P & Ps.	
8113		
CII.8a	The complaint process includes intake, investigation, corrective action as applicable, complaint resolution, written reports, organizational trending, & follow-up	
CII.8b	Resolution/outcome information is communicated to the complainant	
CII.8c	. Staff are aware of mechanisms for receiving & resolving complaints	

	Description	IN PLACE		-	Comments
		YES NO NA	AA.	AVD	
	TROISTABLE INFORMAL (NAME) SECURCE SECURCE (SECURCE SECURCE SE				
5	The organization has abundane. A sopropriate furnar resources to man case load & workend demands (
CIII.1a	CIII.1a A non-discriminatory recruitment & selection process, as defined in P&Ps, is adhered to		×		
CIII.1b	CIII.1b Personnel are employed & assigned responsibilities commensurate with their education & experience				
CIII.1c	CIII.10 As experiential qualifications specific to the position		×		
CIII.1d	CIII.1d Employee turnover rates are monitored, tracked, & trended as applicable				
CIII.1e	CIII.1e The opportunity for exit conferences are:		×		
	1) Offered to terminating employees as applicable			_	
	2) Documented & trended as applicable				
CIII.1f	Personnel policies/conditions of employment are provided to employees::				
	1) At time of hire				
	2) Thereafter, as updates/revisions are needed				
CIII.1g	CIII.1g Evidence of the following employee information is maintained in accordance with organizational policy & regulatory guidelines:				
_	1) Individual job qualifications				
	2) Verification of education/training			_	
	3) Certification for specially areas of practice as applicable				
	4) Statement of formal training for non-professionals				
	5) Two (2) reference checks				
	6) Pre-employment interview(s)				
	7) Current licensercertification as applicable				
	8) Validation of clinical competency skills testing as applicable				-
	a) Time of hire	:			
	b) Annuaí				
	9) Validation of performance evaluation at end of probation & annually				
	10) Validation of malpractice coverage for independent contractors				
	11) Validation of completion of orientation (time of hire & re-assignment)				
_	12) Vaildation of signed & dated confidentially statements				
	13) Validation of in-service/continuing education participation as applicable				
	14) Validation of exit interview as applicable				
	15) Miscellaneous items per state, federal or organizational requirements				
	16) Criminal background checks in accordance with organization P $lpha$ P and local and/or state law				
	17) Immigration & naturalization statement (I-9)				
CIII.1h	CIII.1h Specified personnel documents and employee health reports may be retained in separate files per organizational policy		×		
CIII.11	CIII.11 An annual written performance evaluation process is completed on all employees by their respective supervisor & includes:			_	
					Caracteristics and the control of th

		100.101	H		
	Description	_		_	Comments
		VES NO	NA AIR	DW PAG	
	1) Supervisor assessment of employee performance in accordance with established criteria (Job Description)				
	2) Achievement of previously established goals				_
	3) On-site evaluation reports/competency testing for clinical/field/service staff				
	4) A signed, dated validation of the process by the employee & employer representative				
CIII.1J	An annual performance evaluation process provides an opportunity for active participation by employees through:				
	1) Employee development planning/new goal setting				
	2) Employee response to evaluation				
CIII.1k			×		
CIII.11			×		
CIII.1m					
ZIIIO					
CIII 2a					
CIII.2b					
	1) Specific services/products to be provided		-		
	2) Contractor is required to adhere to applicable primary organization P&P's				
	3) Assurance by the contractor of the education, training, qualifications & identification of personnel designated to provide care, services & products		-		
	4) Mechanisms for the contractor parties to participate in Performance Improvement activities as applicable				
	5) Procedures for the documentation & submission of documented notes that verify the provision of services/products in accordance with the written service contract.				
	6) Procedures for the submission of bills & related information & reimbursement for care, services & products provided				
	7) Effective dates of the contract, including terms of renewal Blor termination MB. Additional service specific contract elements are addressed under contracts in service specific standards				
EIII0	Trigogamizatoris soutras of financial supportare mandrat & nontroction an organizatoris consum the availability of documentum				
CIII.3a	Financial P&Ps govern fiscal activities of the organization				
CIII.3b	The chief financial manager has the appropriate qualifications, credentials & expertise to oversee, manage & direct the fiscal operations of the creativation.				
CIII.3c					
CIII.3d					
CIII.3e	Financial management tools are used to provide operational feedback to administrative & management personnel, financial committees & the GB				
CIII.3f			×		
CIII.3g	An annual external review is required & conducted		×		
100	Amanokalmanagement intromation system is used to document & monitoral financia timely reports to all levies within the organization				
CIII.4a	The financial reporting system produces detailed data re: actual transactions specific to care, services & products provided by each program including siteliocation activity				
CIII.4b			×		
CIII.4c	Internal financial controls are in effect				
	1) Internal audit procedures & annual review of budget are conducted				

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3	

Comments

YES NO NYA AIR AND

CIII.4d Reimbursable services are billed on a timely basis in accordance with designated fee structures & are monitored, tracked, & aged

2) Adherence to organizational financial P&Ps is monitored

CIII.4e Payroll & vendor disbursements are recorded & processed in a structured & timely manner

CIII.5a

CIII.6a A manual or automated system utilizes established standards & defined data elements for the collection & processing of information

IN PLACE

Description

	Description	IN PLACE			Comments
		YES NO	WA AIR	R A/O	
		(STREAMSTER)			
Strangolivia Strangolivian	S <mark>rategiccia</mark> uning reflectsthe organizational mission & includes a comprehensive evaluation of both internal & external environments	NJ240-openio	×		
ment budge	CIV.1a Current budgetary, business & marketing activities are integrated into the process				
assessme	CIV.1b An assessment of the organization's strengths, weaknesses, opportunities & threats is conducted on a periodic basis				
ammalen	Anamusi exclusion of the organization provides the basis to future planning.	angerenner		×	
Organizationa evaluated	Organizational policies drive the process for the annual program evaluation by an authorized group & identify the components to be evaluated				
The complexity of the or utilization and includes:	The complexity of the organization & the scope of care, services & products provided define the parameters for data collection & utilization and includes:				
1) Service/product data	buct data				
2) Risk management data	ement data				
3) Human resources data	ourres data				
4) Financial data	ala				
riances fro	CIV 2c Variances from usual & expected patterns of performance are analyzed & explained				
ie Annual E	The Annual Evaluation Report is presented to advisory bodies & GB as appropriate				
ne Annual Ev	CIV.2e The Annual Evaluation Report is retained as an administrative record studies are obtained & retained on file in the organization				



STANDARDS OF EXCELLENCE

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INTRODUCTION TO CHAP PHARMACY STANDARDS

In keeping with its goal of elevating the quality of all community health care in the United States, the Community Health Accreditation Program, Inc. (CHAP) continually reviews and revises the "Standards of Excellence" to ensure currency with and relevance to the community health care industry. The service-specific Pharmacy Standards 2004 Edition are designed to:

- Establish standards of excellence for all types of Pharmacy services (Open Door, Long Term Care, Mail-Order, Internet, Specialty, Compounding, Infusion)
- Promote ease of application, interpretation and use of standards
- Emphasize the importance of the interests and rights of Pharmacy clients
- Strengthen the long-term viability of all types of Pharmacy organizations
- Advance the recognition of the Pharmacy organization as an integral component of the national health care delivery system

The re-engineered Pharmacy Standards of Excellence, 2004 Edition, address the scope, complexity and challenges of providing comprehensive Pharmacy services in a variety of community-based settings. When used in conjunction with the CORE Standards, 2004 Edition, compliance is ensured with:

- Pharmacy regulatory requirements
- Regulatory requirements that address the health and safety of employees and clients

CHAP standards incorporate most current professional, clinical, industry and regulatory standards and/or requirements.

Underlying Principles

Four key principles form the framework for the revised standards:

I. Structure and Function

III. Resources

II. Quality

IV. Long Term Viability

The four key "Underlying Principles" (UP) continue to drive each set of the CHAP Standards of Excellence. Sub-categories in each section further define the content. The four key underlying principles are used consistently throughout the CHAP accreditation documentation process in the Standards, Self-Study, Workbooks and Site Visit Reports.

- UP I. THE ORGANIZATION'S STRUCTURE AND FUNCTION CONSISTENTLY SUPPORTS ITS CONSUMER ORIENTED MISSION AND PURPOSE.
 - A. Statement of Pharmacy Scope of Products/Services
 - B. Organizational Structure And Functional Mechanisms
 - C. Intra-Organizational Relationships
 - D. Pharmacy Program Director
 - E. Pharmacy Specific Policies and Procedures
 - F. Ethical Issues
 - G. Student Education/Research
- UP II. THE ORGANIZATION CONSISTENTLY PROVIDES HIGH QUALITY SERVICES AND PRODUCTS.
 - A. Public Disclosure, Client Rights, Ethical Standards
 - B. Services Provided
 - C. Emergency Preparedness & Response
 - D. Access to Services/Inter & Intra Organization Coordination
 - E. Assessment, Plan of Care, Verbal Orders
 - F. Client Records
 - G. Effectiveness of Services
 - H. Health & Wellbeing of Employees & Clients
 - I. Complaints
- UP III. THE ORGANIZATION HAS ADEQUATE HUMAN, FINANCIAL, AND PHYSICAL RESOURCES TO ACCOMPLISH ITS STATED MISSION AND PURPOSE.
 - A. Human Resources Support Workload Demand
 - B. Staffing Contracts
 - C. Financial Resources
 - D. Physical Facilities
 - E. Information Systems
- UP IV. THE ORGANIZATION IS POSITIONED FOR LONG TERM VIABILITY.
 - A. Strategic/Operational Planning
 - B. Annual Evaluation of the Pharmacy Operations and Structure
 - C. Innovations

As you study and apply these standards to your own organization, give consideration to the following "TEMES" that flow through all sections of the CHAP Standards of Excellence and Self Studies.

Composition of a Standard

Each standard statement may be comprised of four (4) parts.

- 1. Standard statement A blueprint for success that recognizes excellence
- 2. Criterion A statement that defines in detail the requirements of the standard
- 3. Element A component of each criterion that delineates requirements
- 4. Sub-element Additional statements that provide more definition of selected elements.

Examples Standard:HMEI.1 Criterion:HMEI.1a Element:1)	
Sub element:(a) (not all standards have sub-elements)	

Main Sources of Evidence

Substantiation of Findings

D = Documents	Clarification
I = Interviews	Verification
O = Observations	Quantification
S = Surveys	

Evidence Guidelines

The Standards are formatted with relevant Evidence Guidelines on pages opposite the standards. The evidence guidelines are not standards or criteria. They are intended to provide guidelines and examples of evidence to the organization and the CHAP site visitor which may be used to determine organizational compliance with the standards. The letter preceding each evidence guideline identifies one of four sources of information to be used by the site visitor in the accreditation process: D, I, O, S.

The Site Visit Report

The Site Visit Report is a written legal document that states the level of compliance by the Pharmacy organization with both the CORE and Pharmacy Standards of Excellence. The composition of the report includes a brief organizational profile, statements of organizational strengths and challenges and the written citations.

Citations include:

Commendation:

A statement indicating that the organization has significantly exceeded

the requirements of a specific standard or criterion.

Required Action:

A statement indicating partial or total non-compliance with a CHAP

standard or criterion. Organizations are required to make changes to

comply with CHAP standard or criterion.

Recommendation:

A statement of advisement that identifies a potential problem related to a standard or criterion that may increase in scope and severity if not

addressed. Organizations are not required to make changes but should

give serious consideration to the recommendation.

. , ,)

DI.

THE PHARMACY ORGANIZATION'S STRUCTURE CONSISTENTLY SUPPORTS A CONSUMER ORIENTED MISSION AND PURPOSE

LEGEND:

- **D DOCUMENTATION**
- I INTERVIEW
- O OBSERVATION
- S SURVEY

- D: A printed definition of the organization's scope of products and services is available. (DI.1)
- D: Governing body minutes document actions taken on the scope of products and services statement:
 - (a) Review and approval within the past twelve months.
 - (b) Revisions and updates as applicable.
 - (DI.a)
- I: Management and staff describe the process for making scope of products and services statement available upon request. (DI.1b)

DI.1	A written statement by the Pharmacy Organization identifies the scope of products and services provided to clients.
DI.1a	The scope of services statement is periodically reviewed, revised and approved by the governing body but no less than every twelve (12) months.
DI.1b	The pharmacy's scope of services statement is made available upon request to clients, referral sources and other interested parties.

LEGEND:

- **D DOCUMENTATION**
- I INTERVIEW
- O OBSERVATION
- S SURVEY

- D: Required County/State/Federal licenses, authority documents, and Medicare/Medicaid/reimbursement certification (if applicable) are current as required. (DI.2a)
 - Note: County/State specific licenses may include Sellers Permit, Occupational License, etc.
- D: Review of recent findings of other reviewing bodies confirm compliance. (DI.2a)
- D: The disclosure statement is current, signed and dated by the chief executive and on file. (DI.2b)
- D: Minutes or other formal governing body documents reflect that the governing body authorized an advisory committee. (DI.2c)
 - Note: Advisory Committee may be the governing body as a whole, a subcommittee of the governing body or a separate committee.
- D: Membership in the advisory committee includes a physician, a pharmacist, a registered nurse and at least one community representative. (DI.2c)
- D: Official documentation or minutes reflect annual review of policies and evaluation of the Pharmacy program. (DI.2c)

DI.2 The Pharmacy Organization has the structure and functional mechanisms necessary to accomplish its stated scope of services.

- DI.2a The Pharmacy Organization has the legal authority to operate and is in compliance with local, state and federal regulations.
 - 1) State Board of Pharmacy License
 - 2) Business License
 - 3) DEA Narcotic License
 - 4) d/b/a, Trade Name registration, if applicable
 - 5) Tax ID number
 - 6) Medicare & Medicaid provider numbers, where applicable
 - 7) Specific county and state required authorities
- DI.2b The Pharmacy Organization is required to prepare and maintain a current written disclosure statement signed by the chief executive, addressing applicable elements as frequently as required by state regulations but no less frequently than every three years.
 - 1) Names and addresses of individuals or corporations having a combined direct or indirect ownership or controlling interest of 5% or more in the organization
 - Names and address of subcontractors in which the organization has a direct or indirect ownership of 5% or more
 - 3) Names and addresses of individuals, who are related as spouse, parent, child or sibling to individuals described in (1) and (2) above
 - 4) Names and addresses of individuals in (1), (2), and (3) above with an ownership or controlling interest in a Medicare or Medicaid facility
 - 5) Names and addresses of officers, directors or partners
 - 6) The circumstances of any criminal offense conviction involving Medicare/Medicaid programs on the part of any person(s) or organization(s) in (1), (2) or (3) above and/or, on the part of any managing employee of the organization
 - 7) The dates of any changes in ownership or control during the previous twelve (12)
 - 8) The dates of anticipated changes of ownership or control in the next twelve (12) months
- DI.2c An Advisory Committee of professionals is authorized by the governing body to advise the organization on policies and to evaluate the Pharmacy Program.
 - 1) Responsibilities of the committee include establishment and annual review of pharmacy policies and participation in the annual evaluation of the Pharmacy program.
 - 2) Membership of the committee includes a physician, a pharmacist, a registered nurse and at least one community representative who is not an employee
 - 3) Committee meeting minutes reflect the committee's fulfillment of its responsibilities
 - 4) The Advisory Committee meets at least once annually.

LEGEND:

- **D DOCUMENTATION**
- I INTERVIEW
- O OBSERVATION
- S SURVEY

DI.2 cont'd

I: Management and staff describe and cite examples of how current clinical and organizational data are assessed and used in revision of policies and practices. (DI.2d)

DI.2d

D1.2d

Systems exist for obtaining and integrating the most current information into the professional practice to be used in planning, evaluation and decision making in all aspects of the program.

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LEGEND:

- **D DOCUMENTATION**
- I INTERVIEW
- O OBSERVATION
- S SURVEY

- D: A current organizational chart is available and clearly delineates the lines of authority and accountability for all organizational positions. (DI.3a)
- I: Staff members are familiar with the organizational chart and state their individual lines of authority and accountability.

 (DI.3a,3b)

DI.3	Intra-organizational relationships of the Pharmacy Organization are clearly defined in writing.
DI.3a	A current organizational chart illustrates the lines of authority and accountability for all administrative, professional, technical, clinical and clerical personnel.
DI.3b	The complexity of the Pharmacy organization's administrative structure is appropriate for efficient delivery of product and service.

LEGEND:

- **D DOCUMENTATION**
- I INTERVIEW
- O OBSERVATION
- S SURVEY

- D: Pharmacy Program Director's resume, diploma, reference checks and current professional license verify compliance with requirements for the position. (DI.4a, DI.4b)
 - Note: The Pharmacy Program Director may be a regional position in multi-state organizations. In that instance, the Program Director would have a current active Pharmacist license in a state. The Pharmacist in Charge at the specific site will have an active Pharmacist license in that state. The Pharmacy Program Director and the Pharmacist in Charge may be the same or separate position in the organization.
- I: Pharmacy Program Director demonstrates knowledge of local, state and federal pharmacy regulations. (DI.4b)
- D: The Pharmacy Program Director's job description and/or policies include responsibilities as specified in elements 1-11, or the responsibilities are clearly delegated to other specific positions. (DI.4c)
- I & O: The Pharmacy Program Director demonstrates understanding of his/her role. (DI.4c)
- D: Written policy and procedure defines assignment of administrative responsibilities in the absence of the Pharmacy Program Director. (DI.4d)
- I: Designated alternate to the Director understands his/her role and describes experiences specific to the alternate roles. (DI.4d)
 - Note: DI.4 may appear to be a duplication of CI.4; however, CI.4 pertains to the CEO of an organization, and DI.4 pertains to the Pharmacy Program Director, which may be the same or separate position in the organization.

D1.4	Authority and responsibility for the overall executive management of the Pharmacy Organization is vested in qualified individuals.
DI.4a	The Pharmacy Program Director is a graduate of a pharmacy program accredited by the American Council of Pharmaceutical Education or has passed a Foreign Pharmacy Graduate Equivalency Examination given by the National Association of Boards of Pharmacy, is currently licensed as a Pharmacist in the state.
DI.4b	A qualified pharmacist with appropriate knowledge, expertise and experience is responsible for the management, direction, coordination and general supervision of all professional services.
DI.4c	The Pharmacy Program Director is responsible for the following areas either directly or by clear delegation:
	 Organizing and directing the Pharmacy program's operations to assure the availability of services and products provided Assuring adequate inventory of pharmaceuticals and supplies necessary to compound and dispense prescriptions appropriately, including periodic inspection for outdated products. Assuring all equipment utilized in the delivery of the organization's products and services is properly maintained Assuring pharmacy services are provided in compliance with applicable laws, regulations, accreditation standards and ethical standards of practice Assuring adequate and appropriate staffing, including recruitment, orientation, inservice education and completion of annual performance appraisal Coordinating with other program areas and managers as appropriate, consistent with organizational structure Assuring the implementation of a pharmacy performance improvement program including evaluation of the home pharmacy program services Assuring Drug Control system consistent with policies and regulatory requirements Assuring appropriate pharmacy supervision at all times Assuring safe and appropriate service policies are developed and implemented

DI.4d A qualified individual is designated in writing to act in the absence of the Pharmacy Director.

LEGEND:

- **D DOCUMENTATION**
- I INTERVIEW
- O OBSERVATION
- S SURVEY

- D: Policies reflect the current practice, professional standards of Service, and scope of service.(DI.5a)
- D: Pharmacy administrative policies and procedures at a minimum address items 1-4. (DI.5b)
- D: Pharmacy operational policies and procedures at a minimum address items 1-25. (D1.5c)
- D: Policy is available and includes temperature, light and security. (DI.5c.1)
- D: Policy is available when the pharmacy has a contractual relationship with a nursing agency. (DI.5c.8)

- DI.5 Pharmacy policies and procedures reflect an emphasis on quality and ethical practice, relate directly to the scope of the Pharmacy program, and ensure client rights, and ethical standards of business and clinical practice.
- DI.5a Organizational literature, policies and procedures accurately reflect the current practice, current professional standards of service and scope of the Pharmacy program.
- DI.5b Pharmacy Program administrative policies and procedures include:
 - 1) Regulatory Compliance
 - 2) Capital Short-fall Contingency Plan
 - 3) Pharmacy Reference Materials
 - 4) Annual Evaluation
- DI.5c Pharmacy Program operational policies and procedures covering the scope of services provided are developed and include at a minimum:
 - 1) Storage of final pharmaceutical products
 - 2) First dose new drug administration
 - 3) Handling investigational drugs
 - 4) Client/caregiver instruction
 - 5) Timely assessment of client eligibility and provision of service
 - 6) Notification of referral source if client does not meet admission criteria
 - 7) Delivery of services/products, as applicable
 - 8) Contents, dispensing and maintenance of infusion emergency kits
 - 9) Acquisition, storage, disposition & dispensing of controlled substances
 - 10) Selection, maintenance, use & control of infusion control devices for drug administration, as applicable
 - 11) Client identification confirmation
 - 12) Availability of latex-free supplies
 - 13) Prescription labeling
 - 14) Materials/Inventory Management
 - 15) Equipment cleaning, testing and tracking
 - 16) After Hours Coverage
 - 17) Dispensing Records
 - 18) Sterile Admixture Procedures for monitoring for medication errors, surface testing, environmental air sampling and product sterility
 - 19) Preparation of injectables from sterile solutions
 - 20) Preparation of injectables from non-sterile powders
 - 21) Preparation of respiratory drugs from non-sterile powders
 - 22) Clinical competency testing
 - 23) Competency testing of sterile product preparation
 - 24) Medication Error
 - 25) Recall

LEGEND:

- **D DOCUMENTATION**
- I INTERVIEW
- O OBSERVATION
- S SURVEY

DI.5 cont'd

- D: Pharmacy clinical policies and procedures at a minimum address items 1 -6. (DI.5d)
- D: Pharmacy quality improvement policies and procedures at a minimum address items 1-4. (DI.5e)
- D: Written policy is available for first dose drug. (DI.5f)

DI.5d

DI.5d

Clinical policies and procedures consistent with professional standards of practice are developed and include at a minimum the following:

- 1) Client Assessment
- 2) Medication Assessment
- 3) Drug Profile Review
- 4) Care Planning, as appropriate
- 5) Development of a comprehensive care plan
- 6) Clinical monitoring

DI.5e

Quality Improvement policies and procedures consistent with professional practice and regulatory mandates are developed and include at a minimum:

- 1) Performance Improvement Plan
- 2) Structure and routine maintenance of compounding areas
- 3) Maintenance of Laminar Flow Hood
- 4) Infection control, safety for preparation, dispensing, disposal of pharmaceuticals

DI.5f

Policies identify when a physician or other qualified professional is required to be present for the administration of the first dose of a new drug to detect, monitor and respond to adverse drug reactions.

LEGEND:

- **D DOCUMENTATION**
- I INTERVIEW
- O OBSERVATION
- S SURVEY

DI.6

- D: Meeting minutes document discussions of and actions taken by the group, as applicable. (DI.6a)
- I &O: Staff demonstrates knowledgeable of and compliance with reimbursement and regulatory guidelines. (DI.6b)

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Evidence Guidelines Page H

DI.6

DI.6 The Pharmacy Organization's business and clinical activities are conducted according to ethical standards.

- DI.6a A designated and qualified group of professionals/individuals address ethical issues relating to the business and clinical practices of the Pharmacy Organization.

 The issues include but are not limited to:
 - 1) Care delivery issues
 - 2) Product and service related issues
 - 3) Billing and collecting issues
 - 4) Medical necessity authorization issues
 - 5) Statistical data trending and tracking issues
- DI.6b Staff are knowledgeable about and carry out their responsibilities for providing products and services in accordance with reimbursement and regulatory guidelines.

LEGEND:

- **D DOCUMENTATION**
- I INTERVIEW
- O OBSERVATION
- S SURVEY

- I: Pharmacy Director/pharmacists describe the process for assuring that clients are fully informed and provide written consent prior to participating in research or investigative studies. (DI.7a)
- D: Written contract or agreements pertaining to Pharmacy educational experiences for non-employees (i.e., students) exist as applicable. (DI.7b)
- D & I: Documents and interviews validate that current research initiatives exist as applicable. (DI.7c)
- D & I: Pharmacy employees publish research findings as applicable. (DI.7d)

DI.7	The Pharmacy Organization contributes to the development and expansion of knowledge in Pharmacy practice, as appropriate.
M. M	
Dl.7a	A Pharmacy Organization participating in research or investigative studies ensures that clients are fully informed and provide written consent.
DI.7b	Arrangements for student education experiences are formalized in written contracts or agreements that specify the responsibilities of the Pharmacy organization and the educational institution.
DI.7c	The Pharmacy organization demonstrates a positive attitude regarding research initiatives and considers requests for research in the area of pharmaceutical practice as appropriate.
DI.7d	The Pharmacy organization encourages the publication of significant outcomes related to the management and practice of pharmacy.

DII.

DII.

THE PHARMACY ORGANIZATION CONSISTENTLY PROVIDES HIGH QUALITY PRODUCTS AND SERVICES

LEGEND:

- **D DOCUMENTATION**
- I INTERVIEW
- O OBSERVATION
- S SURVEY

DII.1

- D: Current Public Disclosure policy includes the element of DII.1a, if applicable, in addition to the elements of CII.1a. (DII.1a)
- D: The Client Bill of Rights statement and/or other admission documents includes elements of DII.1b in addition to the elements of CII.1b. (DII.1b)
- D: Record review confirms that the Client Bill of Rights is signed by the client or client representative and is filed in the record. (DII.1c)
- O: Observation of the open door pharmacy validates that the Client Bill of Rights is posted in a public area. (DII.1d)
- D: Record review validates that pharmacy products and services are provided to clients consistent with the organization's stated scope of service. (DII.1e)

- DII.1 The Scope of Services drives the activities of the Pharmacy Organization and ensures public disclosure, client rights, and ethical standards of business and clinical practice.
- DII.1a The written public disclosure policy makes the Annual Report for C Corporations, if applicable, available to the public on request.
- DII.1b A written Client Bill of Rights statement or other written admission documents are provided to the client or the client's representative at the start of care or at the time of initiation of care and include the right to be fully informed of:
 - 1) Services and products being provided
 - 2) Organization's ownership and control
 - Names and qualifications of individuals providing products and services

And the right to:

- 4) Participate in one's own care
- 5) Continuity of products and services
- 6) Education about the products and services to be provided
- 7) Refuse part or all of the products and services to be provided
- 8) Receive products and services in a timely manner and in accordance with organizational policy
- 9) Be referred to another organization
- 10) Be free from abuse or exploitation of any kind
- 11) Receive information, both verbal and written, in an understandable format.
- DII.1c The Client Bill of Rights is signed by the client or a representative of the client and made a permanent part of the client's record.
- DII.1d For clients receiving open door pharmacy services, the Client Bill of Rights is posted in a public area accessible to those clients.
- DII.1e The Pharmacy organization's products and services are provided in accordance with the organization's scope of services.
 - 1) Statistical reports confirm that products and services are provided consistent with the Pharmacy organization's scope of services.
 - 2) Staff at all levels are knowledgeable about and support the Pharmacy organization's mission and scope of services.

LEGEND:

- **D DOCUMENTATION**
- 1 INTERVIEW
- O OBSERVATION
- S SURVEY

DII.2

- I & O: Interview and observation of practice confirms that the pharmacy organization is providing services as defined in DII.2a.
- D: Job descriptions and/or other policies identify duties and responsibilities of each discipline, which are consistent with national practice standards. (DII.2b)
- I & O: Interviews and direct observation of staff in practice confirms staff understanding and fulfillment of responsibilities. (DII.2b)
- D: Clinical record documentation by respective disciplines verifies fulfillment of assigned responsibilities. (DII.2b)

DII.2 Pharmacy services are provided in accordance with organizational policies and procedures, to clients in their place of residence, and may include dispensing at the pharmacy site, transported delivery to home/client site or mailed delivery.

DII.2a Pharmacy services include but are not limited to:

- 1) Interpretation and evaluation of the prescription order
- 2) Drug product selection, compounding, dispensing, storage
- 3) Distribution of drugs and devices
- 4) Advising the prescriber and other health care professionals, the client and/or caregiver as to therapeutic actions, utilization and possible adverse reactions and interactions in order to encourage a positive client outcome.
- DII.2b Pharmacy services are provided by or under the direction and supervision of a qualified pharmacist.
 - Professional pharmacy service is provided by a registered pharmacist and include:
 - (a) Overseeing the drug control system including:
 - 1) Receipt of prescription drugs and prescription orders
 - 2) Storage of medications
 - 3) Packaging of medications
 - 4) Preparation and dispensing of prescriptions
 - 5) Labeling
 - 6) Preparation of prescriptions for delivery
 - (b) Instruction/counseling clients and caregivers regarding specific drug therapy including possible adverse reactions and/or interactions
 - (c) Providing information regarding the safe and appropriate use of medications to other health care professional
 - (d) Identifying appropriate outcomes of drug therapy
 - (e) Consulting on drug therapy and coordinating with other health care professionals
 - (f) Monitoring and documenting ongoing drug therapy including the assessment of:
 - 1) The therapeutic appropriateness of the choice of drug(s)
 - 2) Therapeutic duplication in the client's drug routine
 - 3) Appropriateness of the dose, frequency and route of administration
 - 4) Adherence to drug regimen
 - 5) Potential drug, food or diagnostic test interactions of disease limitations to drug use
 - 6) Laboratory or clinical monitoring methods to detect drug effectiveness, side effects, toxicity or adverse effects
 - 7) Preparing and maintaining clinical records
 - (g) Prescribing activities consistent with state/federal regulations.
 - 2) Pharmacy technical services are provided by pharmacy technicians who have been trained for all tasks performed in compliance with state law, job description and organizational policy.

LEGEND:

- **D DOCUMENTATION**
- I INTERVIEW
- O OBSERVATION
- S SURVEY

DII.2 cont'd.

- 1: Procedures for ensuring availability of drugs, supplies and Equipment are described. (DII.2c)
- I: Job descriptions and/or policies include the indicated delivery personnel responsibilities (DII.2d)
- 1 & O: Interviews and direct observation of delivery services during home visits confirms staff understanding and fulfillment of responsibilities. (DII.2d)
- I: Clients relate satisfaction with delivery services. (DII.2d)
- I: Procedures for ensuring availability of drugs, supplies and infusion devices when not available from the organization are described. (DII.2e, DII.2f)

- DII.2c The Pharmacy Program provides pharmaceutical care, related supplies and equipment to clients.
- DII.2d Delivery services are provided directly or by arrangement in compliance with laws and regulations and include:
 - 1) Safe and clean transport of pharmaceuticals and supplies to and from client homes/designated sites.
 - 2) Timely delivery of pharmaceuticals and supplies
 - 3) Record keeping
 - 4) Setting up equipment in client homes, if applicable
- DII.2e The organization has a process in place for assuring the availability of drug and supplies to clients in their designated sites not available from the organization.
- DII.2f The organization has a process in place for assuring the provision of infusion devices to clients in their homes/designated sites when not available from the organization.

LEGEND:

- **D DOCUMENTATION**
- 1 INTERVIEW
- O OBSERVATION
- S SURVEY

D11.3

- I: Staff describe how necessary services (pharmacy and delivery) are made available to clients at all times (on-call practices). (DII.3a)
- D: Review of documents (complaint log, client satisfaction survey, on-call logs) validate that response times are consistent with policies and meet client needs. (DII.3a)
- D & I: An on-call plan is available, and staff describe the on-call plan. (DII.3b)
- O: Testing of the on-call plan validates that the organization is in compliance with its on-call coverage plan and policy.

 (DII.3b)
- I: Client/family describes service availability after hours. (DII.3c)
- D: Written contingency plan protocols are available and include items 1 3. (DII.3d)

DII.3

DII.3	Clinical services and products are accessible and available to clients on an emergency basis 24 hours a day, 7 days a week.
DII.3a	The Pharmacy Organization is accessible and responsive to the needs of Clients during normal work hours and after hours which includes:
	 Timely telephone response Timely on-site response, if indicated Product and service delivery prior to scheduled use
DII.3b	There is a plan for on-call coverage for after hours, weekends and holidays.
DII.3c	Clients are informed of the process for accessing service during normal work hours and after hours.
DII.3d	Written contingency plans delineate protocols for prioritizing delivery of product and services to clients including:
	1) Disaster preparedness

- 2) Inclement weather events
- 3) Unexpected critical staffing deficits

LEGEND:

- **D DOCUMENTATION**
- I INTERVIEW
- O OBSERVATION
- S SURVEY

DII.4

- D: Written policy identifies admission criteria and referral process when the organization does not provide the needed product or service. (DII.4a)
- D: Policies and procedures define the responsibilities of the pharmacists, and record review confirms documentation by the pharmacist. (DII.4b)
- O: Observation validates assumption/fulfillment of responsibilities. (DII.4b)
- D: Policies and/or procedures define the responsibilities for service coordination. (DII.4c, DII.4d)
- D: Review of records confirms that care coordination activities are performed. (DII.4c, DII.4d)

Note: Appropriate referrals involves referrals for additional services as indicated. (DII.4d.4)

- D: Client records document interdisciplinary coordination as appropriate. (DII.4 e)
- I & O: Pharmacists indicate how drug profile information is made accessible to other appropriate professionals, the mechanisms for coordination, the procedures for coordinating delivery of medications, equipment and supplies and that that they are delivered and available as appropriate. (DII.4e)

DII.4 The Pharmacy Organization admits clients whose service needs can be met and ensures continuity of care/service through coordination of client services.

- DII.4a Clients are admitted to service and continued on service, based on the reasonable expectation that their needs can adequately and safely be met by the program.
- DII.4b A pharmacist assumes responsibility for planning, implementing therapy, evaluating the outcomes of therapy provided as applicable and documenting in the client record.
- DII.4c Care is coordinated for each client by the pharmacist and includes at a minimum:
 - 1) Periodic verbal, telephone or electronic communication with other professionals involved in the care of the client
 - 2) Timely documentation of the coordination of care activities
 - 3) Involvement of the client/client representative when indicated
- DII.4d For other than open door pharmacies, care coordination includes elements 1-3 of DII.4c plus the following additional components:
 - 1) Initial assessment of the client, family and, if applicable, the home environment
 - 2) Development of a plan of care
 - 3) Determination of expected outcomes
 - 4) Appropriate referral and follow up
 - 5) Implementation of the care plan
 - 6) Ongoing evaluation
 - 7) Plan of termination of care
- DII.4e The pharmacist works collaboratively with other health care professionals to assure coordination of care.
 - 1) The client drug profile information is available to professionals participating in the care of the client:
 - a) at a minimum, during operating hours for all pharmacies
 - b) at all times, including after hours for infusion pharmacies
 - 2) The delivery of medications, equipment, and supplies is coordinated with other professionals involved with the care of the client to ensure that proper products and supplies are available when needed.

LEGEND:

- **D DOCUMENTATION**
- I INTERVIEW
- O OBSERVATION
- S SURVEY

DII.5

- D: Client assessment policies and record review validate the inclusion of specified items for all pharmacies. (DII.5a)
- D: Client assessment policies and record review validate the inclusion of specified items in DII.5a and DII.5b for infusion and long term care pharmacies. (DII.5b)
- D: Medication assessment policy and record review validate the inclusion of elements 1-6. (DII.5c)
- D, I &O: Interview, observation and record review confirm that client assessments and medication assessments are conducted prior to dispensing. (DII.5a,DII.5b,DII.5c)
- D: Policies establish mechanisms for obtaining written physician verification of and approval for verbal orders. (DII.5d)
- D: Record review documents that required prescriptions were received prior to dispensing medications. (DII.5d)
- D: Record review documents that verbal orders are taken and signed by the Pharmacist prior to filling orders. (DII.5d)

DII.5 The Pharmacy Organization defines the plan of care process, including assessments, physician oversight, dispensing and client training.

DII.5a An initial client assessment is made by the pharmacist prior to dispensing which includes at a minimum:

- 1) Name, address, telephone number, gender, age/date of birth of client
- 2) Allergies/sensitivities of client
- 3) Medication Order
- 4) Physician name, telephone number
- DII.5b For infusion and long term care pharmacies, an initial client assessment is made by the pharmacist prior to dispensing which includes elements 1-4 of DII.5a plus the following additional components as appropriate:
 - 1) Chief Complaint/Medical history/Diagnosis
 - 2) Height and weight of client
 - 3) Client Infection, Sensitivities obtained as available
 - 4) Significant Lab Results
- DII.5c A medication assessment is made by the pharmacist prior to dispensing which includes at a minimum:
 - 1) Potential drug interaction
 - 2) Potential for poly-pharmacy
 - 3) Appropriate dose and frequency
 - 4) Appropriate time of administration
 - 5) Appropriate route and method of administration
 - 6) Appropriate infusion device of administration, if applicable
- DII.5d Pharmaceuticals are dispensed according to the prescription of a physician or physician designee legally authorized to prescribe in compliance with state regulation:
 - 1) Written, verbal or faxed prescriptions are available to the pharmacist before dispensing the medication
 - 2) Verbal orders taken from a physician or physician designee are recorded and signed by the pharmacist prior to filling the medication order

LEGEND:

- **D DOCUMENTATION**
- I INTERVIEW
- O OBSERVATION
- S SURVEY

DII.5 cont'd

- D: Written policy is available and includes elements 1-11. (DII.5e)
- D: Drug labels include the indicated items. (DII.5e)
- D: Plans of care are available for each client and include items 1-6. (DII.5f)

Note: Review by physician may include review of orders, copies of plans of care mailed/faxed to physician. (DII.5f.6)

- D: Written policy and procedure define the process for confirming client Identification. (DII.5g)
- I & O: Pharmacy and delivery staff explain the process for confirming client identification prior to dispensing. (DII.5g)
- D: Policies and procedures with specifications detailed are available for emergencies for pharmacy infusion services. (DII.5h)
- I: Staff are familiar with emergency procedures and provide examples of their appropriate use. (DII.5h)
- D: Drug information and instructional materials are prepared for all types of products and services provided. (DII.5i)
- D: Review of documents validates that the client or caregiver was instructed in self-administration of therapy when self-administration was indicated. (DII.5j)
- D: Client training/education is documented. (DII.5i, DII.5j)
- I & O: Clients understand their regimes. (DII.5i, DII.5j)

- DII.5e All pharmaceutical products dispensed to clients are appropriately labeled according to state and federal regulations and, at a minimum, include:
 - 1) Name, address and telephone number of the pharmacy
 - 2) Date the prescription was dispensed
 - 3) Expiration date of the medication
 - 4) Pharmacy's prescription number
 - 5) Client's full name
 - 6) Name of the drug, brand, strength, if applicable, and the amount dispensed
 - 7) Directions for use
 - 8) Prescriber's name
 - 9) Other pertinent information or cautionary labels
 - 10) Rate, route and method of administration
 - 11) For IV mixture drugs, rate of administration and expiration date of the fluid
- DII.5f A comprehensive plan of care is developed by infusion pharmacies which includes:
 - 1) Establishment of Therapy Specific Goals
 - 2) Determination of Expected Outcomes
 - 3) Determination of Educational Needs
 - 4) Establishment of Monitoring Plan
 - 5) Determination of Achievement of Goals/Outcomes
 - 6) Periodic Review by Prescribing Physician
- DII.5g Client identification is confirmed prior to dispensing.
- DII.5h For pharmacy infusion services, there are policies and procedures for emergency situations including, ordering of emergency kits with appropriate drugs by the physician and placement of these kits in the client's home, where appropriate.
- DII.5i Drug information and instructional materials for administration are provided to the client or client caregiver at the time of dispensing.
- DII.5j Client training/education in self-administration is provided upon initiation of therapy, as applicable

LEGEND:

- **D DOCUMENTATION**
- I INTERVIEW
- O OBSERVATION
- S SURVEY

DII.6

- D: Client records document that appropriate clinical services were provided to clients. (DII.6a)
- D: Client records are current and include elements 1-4. (DII.6a)
- D: Client records document adherence to all clinical written policies and procedures. (DII.6a)
- D: Client drug profiles are current and include items 1. a-h. (DII.6a.1)
- D: Pharmacy dispensing records include items 2.a-k. (DII.6a.2)
- D Records document adherence to first dose policy for new drug therapies. (DII.6a.2)
- D: Pharmacy dispensing records for other than open door pharmacies include items a-k of DII.6a.2 and elements a-d of DII.6a.3.
 (DII.6a.3)

Note: Compounding instructions may be found in protocols, policies and/or specific instructional forms. (DII.6a.3c)

Documentation exists that a pharmacist oversees the process for dispensing, i.e., Pharmacist signature/initials on the label, on the compounding sheet, etc.(DII.6a.3d)

- D: Narcotic records include items specified. (DII.6a.4)
- I & O: Controlled substance records are maintained in compliance with state, federal and practice regulations. (DII.6a.4)

DII.6 Client records are maintained for each client and are utilized as a tool for coordination of services, as legal documentation of products and services provided and as a basis for billing and reimbursement procedures.

DII.6a Adequate and appropriate pharmacy records are maintained

- 1) Drug profiles are maintained for all clients and include the following information:
 - (a) Name, gender, birth date and weight (when appropriate)
 - (b) Address and client identification
 - (c) Allergies or sensitivities
 - (d) Diagnosis
 - (e) Current drug regimen
 - (f) Dosages
 - (g) Relevant clinical information regarding drug therapy
 - (h) Physician's name
- 2) Dispensing records are maintained for pharmaceuticals which include:
 - (a) Client's identification, name and address
 - (b) Name of medication
 - (c) Strength and dosage form
 - (d) Quantity dispensed
 - (e) Physicians' name
 - (f) Dispensing pharmacist/technician identification
 - (g) Prescription number
 - (h) Date dispensed
 - (i) Directions for use
 - (j) Expiration date
 - (k) Number of refills authorized
- 3) Dispensing records for other than open door pharmacies are maintained for pharmaceuticals which include elements a-k of DII.6a2 plus the following:
 - (a) Lot number(s) of drugs
 - (b) Date of the addition(s) to intravenous admixture drugs
 - (c) Special compounding instructions as applicable
 - (d) Documentation of verification procedures
- 4) Controlled substance records are maintained in accordance with state, federal and practice regulations documenting that:
 - (a) A controlled substance inventory is performed in compliance with state or federal regulation.
 - (b) The pharmacist in charge is held accountable for the exact count of Schedule II pharmaceuticals
 - (c) The pharmacist in charge is held accountable for an approximate count of Schedule III, IV, and V pharmaceuticals.

LEGEND:

- **D DOCUMENTATION**
- I INTERVIEW
- O OBSERVATION
- S SURVEY

DII.6 cont'd.

- D: Policy is current and describes signature authentication. (DII.6b)
- I: Records/system administrator describes the inclusion of the 9 items in the ongoing process of ensuring protection of data. (DII.6b)
- O: Pharmacy staff protect data consistent with policy and state law. (DII.6b)
- I & O: A back-up and storage system is in place. (DII.6b)

- DII.6b Automated clinical record systems ensure consistent and ongoing protection of data.
 - 1) Written policy describes signature authentication in accordance with individual state law
 - 2) Safeguards prevent unauthorized access to inputted information
 - 3) Individual and protected access codes are assigned to individuals designated to perform data entry
 - 4) Automated programs designate and control areas of access by authorized personnel based on a personal identifier and position in the organization
 - 5) The computer's internal clock designates date and time of entries
 - 6) Automated controls prevent a change in entry, allowing only corrections
 - 7) Hardcopies of automated data are retrievable by designated personnel
 - 8) A system for validation of inputted data is in place
 - 9) An automated system for backup and storage of data is controlled, and the data is stored in a safe environmental place.

LEGEND:

- **D DOCUMENTATION**
- I INTERVIEW
- O OBSERVATION
- S SURVEY

DII.7

- I: The Pharmacy Director describes the performance improvement process for the pharmacy program. (DII.7a)
- D: Evidence exists of utilization of performance improvement findings to resolve problems and improve quality of service/products.

 (DII.7a)
- D: The performance improvement program include items specified in DII.7a.
- D: The performance improvement plan includes items specified in DII.7b.
- D: Evidence exists of monitoring and analysis of findings as specified in DII.7c.
- I: Pharmacy Director and staff describe use of findings to identify problems and to improve performance. (DII.7c)
- D: Staff orientation and in-service programs validate discussion of improvement program and indicators. (DII.7d)
- D & I: When the pharmacy is part of a larger organization, evidence is provided demonstrating integration of quality improvement plans. (DII.7e)

DII.7 The adequacy, appropriateness, effectiveness and outcomes of products, services and supplies provided are routinely assessed.

- DII.7a The Pharmacy Program has a formalized quality improvement program which is designed to:
 - 1) Identify desired outcomes
 - 2) Identify strategic and at-risk activities
 - 3) Establish monitoring parameters for these activities
 - 4) Establish minimal standards or criteria to be met
 - 5) Describe methods used to improve the quality of service and to achieve the desired outcomes.
- DII.7b The Pharmacy Program has a written performance improvement plan which includes:
 - 1) Description of specific monitoring and evaluation activities
 - 2) Specification of how results are to be reported and evaluated
 - 3) Identification of appropriate follow-up mechanisms when thresholds are exceeded
 - 4) Delineation of individual responsibilities for each aspect of the program.
- DII.7c The Pharmacy Program's performance improvement program includes but is not limited to:
 - 1) Monitoring for medication errors
 - 2) Monitoring and analysis of the findings from surface testing, environmental air sampling and end product testing that includes sterility and pyrogens.
- DII.7d Staff orientation and in-service programs integrate a focus on quality.
- DII.7e The Pharmacy Program's performance improvement plan is integrated into the overall organizational quality improvement plan, as applicable.

LEGEND:

- **D DOCUMENTATION**
- I INTERVIEW
- O OBSERVATION
- S SURVEY

DII.8

- D: Written policies exist and include items 1-10. (DII.8a)
- D: Observation of staff performing responsibilities confirms that staff adhere to infection control and safety policies and procedures. (DII.8a)
- D: Record review confirms that home environment assessments were conducted when indicated and that safety hazards were identified and precautionary instructions were provided to the client and documented. (DII.8b)
- D: Policy requires the designated stipulation for the disposal of controlled substances. (DII.8c.1)
- D: Records confirm adherence to policy. (DII.8c.1)
- D: A Material Safety Data Sheet clearly outlines protocols for disposal of hazardous products. (DII.8c.2)
- O: The Material Safety Data Sheet is available in the pharmacy. (DII.8c.2)
 - Note: The Material Safety Data Sheet information may be available on the pharmacy website as long as each pharmacy employee has access to the information.
- D: Written instructions regarding disposition of hazardous substances in homes are provided to appropriate clients. (DII.8c.3)
- I: Staff and client are aware of disposition procedures for hazardous Substances, if indicated. (DII.8c.3)
- D. Records confirm adherence to policy and regulation. (DII.8c.4)
- D: Client instructions regarding preparation of sterile solutions, storage methods, and durations are documented. (DII.8d)
- I: Clients preparing sterile solutions at home are able to describe appropriate preparation and storage precautions. (DII.8d)

DII.8

DII.8 The health and well being of employees and clients is promoted and maintained through education and implementation of current infection control policies and safety measures.

- DII.8a Infection control and safety measures for the preparation, dispensing and disposal of pharmaceuticals include but are not limited to:
 - 1) Observation of standard precautions
 - 2) Adequate hand hygiene/hand washing
 - 3) Procedures for preventing exposure to blood borne pathogens
 - 4) Glove, gown and eye shield use while compounding hazardous products and chemotherapeutic substances
 - 5) Use of aseptic technique
 - 6) Appropriate use of particulate and/or bacterial filtration
 - 7) Hood decontamination practices
 - 8) Venting of the laminar flow hood outside the building or use of a Class II Biological Safety Cabinet when compounding cytotoxic drugs
 - 9) Proper disposal of needles used in the preparation of pharmaceuticals done by disposing of needles in a tamper proof, puncture resistant container
 - 10) Proper disposal for hazardous waste products
- DII.8b When applicable, the home environment is assessed to evaluate potential safety hazards and to instruct the client and/or those associated with the care of the client about safety precautions. The assessment and client teaching is documented in the client's record.
- DII.8c Disposal of outdated drugs, controlled substances or hazardous wastes is documented and conforms to state and federal requirements.
 - 1) Controlled substances are returned to the Drug Enforcement Administration if required. Documentation of the disposal of controlled substances on site is witnessed by two individuals and includes the amount and type of the drug.
 - 2) Material Safety Data Information is kept in the pharmacy and identifies procedures for disposal of hazardous products
 - 3) Clients are instructed regarding the proper disposal of hazardous products in the home
 - 4) Records are maintained, as required
- DII.8d When clients and caregivers prepare sterile preparations in the home, they are instructed verbally and in writing regarding safeguards against microbial contamination, including, but not limited to the following:
 - 1) Instructions regarding the preparation of the sterile solution
 - 2) Storage methods
 - 3) Duration and stability of the prepared solution

LEGEND:

- **D DOCUMENTATION**
- I INTERVIEW
- O OBSERVATION
- S SURVEY

DII.8 cont'd

- D: Written infection control and safety policies for equipment/delivery service are available. (DII.8e)
- I & O: Staff demonstrate an understanding of infection control procedures and policies. (DII.8f)
- D: Policies specify elements 1 5 of DII.8f. (DII.8f)
- D: Policies specify maintenance, testing, and repair specifications for each type of equipment. (DII.8f)
- I & O: Equipment is maintained, tested, and repaired according to manufacturer's recommendations. (DII.8f)
- D & O: Review of records and observation of practice confirms adherence to organizational policies and that activities are conducted on a routine basis. (DII.8f)

DII.8e

- DII.8e Infection control and safety control policies are established and implemented for the equipment/delivery service, including:
 - 1) Maintenance, testing and repair of equipment according to manufacturer's guidelines
 - 2) Cleaning and storage of reusable equipment between usage
 - 3) Inspection of equipment prior to delivery.
- DII.8f The Pharmacy Program that prepares compounded sterile products conducts the following activities on a routine basis:
 - 1) Routine disinfection and quality testing of direct compounding environment
 - 2) Visual confirmation of personnel processes regarding gowning, and other infection control/safety measures
 - 3) Review of orders and packages of ingredients to assure correct identity and amounts of ingredients
 - 4) Visual inspection of compounding sterile products
 - 5) Media-fill test procedure performed at least annually for each person

LEGEND:

- **D DOCUMENTATION**
- I INTERVIEW
- O OBSERVATION
- S SURVEY

DII.9

- D: Documentation validates that the complaint process includes elements 1-9. (DII.9a)
- D: Review of complaint log validates that complaints have been responded to consistent with the organization's policy and process. (DII.9a)

Pharmacy CHAP, Inc. DII.9 Client complaints and concerns are responded to and resolved in a timely manner.

DII.9a The complaint process includes:

- 1) Designation of the individual(s) responsible for responding to the complaint
- 2) Procedures for responding to complaints
- 3) Time frame for responding to complaints
- 4) Assurance that corrective action is taken as appropriate
- 5) Assurance that client and family rights are protected
- 6) Follow-up activities
- 7) Resolution of the complaint
- 8) Complainant is informed of the outcome
- 9) Trending of justified complaints

DIII.

THE PHARMACY ORGANIZATION HAS ADEQUATE HUMAN, FINANCIAL, AND PHYSICAL RESOURCES, WHICH ARE EFFECTIVELY ORGANIZED TO ACCOMPLISH ITS STATED MISSION

LEGEND:

- **D DOCUMENTATION**
- I INTERVIEW
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- S SURVEY

DIII.1

- D: Staffing assignments are available. (DIII.1a)
- I: Mechanisms for evaluating workload demands are described. (DIII.1a)
- I: Mechanisms for employee selection are described. (DIII.1b)
- D: Documentation of required elements 1-10 validates compliance and inclusion in the personnel files, health files, or the administration files. (DII.1b)
- D: Records include diplomas/transcripts, current licenses and continuing education attendance (if required) for all clinical/professional staff. (DIII.1b.3, 4, 5)
- D: Documentation of certification or adequate training is available for Pharmacy Technicians and Delivery personnel identifying training provided for all tasks performed by the technician and the Driving personnel. (DIII.1b.6, 8)
- I: Delivery and equipment service personnel selection process is described, including driving record checks, and compliance with relevant motor carrier safety regulations. (DIII.1b.7)
- I: Mechanisms for assessing and updating clinical competencies/skills are described. (DIII.1c)
- D: Documentation of clinical competency/skill assessment at time of hire and annually thereafter is available. (DIII.1c)
- D: Documentation of clinical competency assessment including elements 1-5 at time of hire and annually thereafter is available. (DIII.1d)
- I; Mechanism for assessing clinical competency is described by manger and pharmacy personnel. (DIII.1d)

DIII.1 The Pharmacy organization has adequate and appropriate human resources to meet workload demands.

- DIII.1a Staffing guidelines are developed and implemented to adequately meet workload demand.
- DIII.1b Qualified personnel are recruited and retained. Documentation is found in the personnel files, health files or administration files of the following:
 - 1) Budgets allocate sufficient funds to ensure staffing at all levels and are maintained to adequately meet workload demands
 - 2) Positions, new and vacant, are filled on a timely basis to sustain organizational performance goals
 - Clinical staff show evidence of graduation from colleges approved or accredited by their respective professional organization
 - 4) Clinical staff maintain and show evidence of current licensure
 - 5) Clinical staff show evidence of continuing education when required
 - Pharmacy technicians show evidence of certification, or have evidence of adequate training, for all tasks performed in conformance with applicable laws
 - 7) Delivery personnel, when utilized, have a clean driving record and maintain a current driver's license
 - 8) Delivery personnel, when utilized, show evidence of adequate training for all tasks performed
 - 9) Professional & technical personnel show evidence that professional skills are assessed and updated
 - 10) Compounding personnel show evidence of skills, training, and competency testing to perform and document compounding duties.
- DIII.1c Clinical competency evaluations are performed to assess employee basic skill levels for all staff providing client care/services:
 - 1) At time of hire
 - 2) Annually, thereafter
- DIII.1d Clinical competency evaluations of pharmacy personnel who use laminar flow hoods and/or Class II Biological safety cabinets are conducted at time of hire and annually thereafter and include at a minimum:
 - 1) Written test to verify employee's understanding of the concepts of aseptic technique
 - 2) Observation of employee's aseptic technique
 - 3) Sterility validation testing for all employees who make sterile products
 - 4) Observation of cleaning, testing and calibration of infusion equipment
 - 5) Observation of cleaning, testing and calibration of compounding equipment

LEGEND:

- **D DOCUMENTATION**
- I INTERVIEW
- O OBSERVATION
- S SURVEY

DIII.1 cont'd

- D: An orientation plan is available and includes elements 1-5. (DIII.1e)
- D & I: There is an appropriate supervision plan for all levels of staff and each employee. (DIII.1f)
- D: Records show documentation of state/organizational required in-service attendance by pharmacists. (DIII.1g)

Note: In-services may be provided by the organization or other approved entities.

D: Records show documentation of organization's provision of annual in-service program and pharmacist's attendance at the in-service.

(DIII.1h)

DIII.1e

- DIII.1e The orientation plan addresses at a minimum:
 - 1) Mission statement
 - 2) Organizational Chart
 - 3) Lines of authority and responsibility
 - 4) Job related responsibilities (job description)
 - 5) Human Resources policies/conditions of employment
- DIII.1f There is adequate supervision of all pharmacy personnel.
 - 1) Professional Pharmacy services are provided by or under the direction and supervision of a qualified Pharmacist.
 - 2) Staffing ratios of pharmacists to pharmacy technicians are in compliance with state regulations.
- DIII.1g Pharmacists show evidence of participation in formal in-service programs required by state regulation and organization policy.
- DIII.1h The organization provides a minimum of one medication safety in-service annually.

LEGEND:

- **D DOCUMENTATION**
- I INTERVIEW
- O OBSERVATION
- S SURVEY

DIII.2

- D: Contracts for Pharmacy services contain all elements in CIII.2a-b, DIII.2a and DIII.2b. (DIII.2b)
- D: Contracts for Delivery services contain all elements in CIII.2a-b, DIII.2a and DIII.2c. (DIII.2c)
- I: Pharmacy Director describes mechanism for assuring compliance with responsibilities. (DIII.2)

Pharmacy CHAP, Inc. 2004/2005 Edition

Evidence Guidelines Page Y DIII.2 Formal written contracts and agreements with other organizations and/or individuals for the provision of pharmacy products and services to pharmacy organization clients detail specific responsibilities of the parties involved.

- DIII.2a Formal written contracts and agreements with other organizations and/or individuals for provision of pharmacy services includes specific responsibilities as defined in CIII.2a-b and, in addition, the following specific responsibilities:
 - 1) Which organization has the authority to accept and terminate client
 - Services provided under contract must be in compliance with professional standards
 - The manner, in which products and services will be controlled, coordinated and evaluated
 - 4) Designation of responsibilities for orientation
- DIII.2b Pharmacy services when provided under arrangement are in accordance with CHAP Pharmacy Standards and are in compliance with CIII.2a-b, DIII.2a and, in addition, include the provisions for:
 - 1) Who is responsible for teaching the client about pharmaceuticals
 - 2) Assurance that personnel meet the pharmacy program's educational and training requirements
 - 3) Maintenance of current licensure and certification where required
 - 4) On site supervision of pharmacy personnel
 - 5) Hours when pharmaceutical services are available to the client, including arrangements for services during "off hours"
 - 6) Time frames for response to new referrals
 - 7) Responsibilities of contractor and contractee, including:
 - (a) Who assesses the need for pharmaceuticals
 - (b) Who contacts the pharmacy
 - (c) Who obtains the written physician orders
 - (d) Who generates drug profiles and to whom they will be made available of those involved with the client's care
 - (e) Who maintains records for investigational drugs and controlled substances
 - (f) Procedure to follow assuring the availability of drugs and supplies to the clients in their home when not available from the pharmacy
 - (g) Mechanisms for evaluating the contracted service
 - DIII.2c Delivery of products and supplies when provided to clients under arrangement are in compliance with CIII.2 a-b, DIII.2a and, in addition, include the provisions for:
 - 1) Ensuring clean and safe transport of equipment and supplies
 - 2) Timely delivery of products and supplies
 - 3) Setting up equipment in client's homes, where appropriate
 - 4) Adequately trained delivery personnel
 - 5) Client education, where appropriate
 - 6) Appropriate documentation

LEGEND:

- **D DOCUMENTATION**
- I INTERVIEW
- O OBSERVATION
- S SURVEY

DIII.3

- D: Policies pertaining to cash management and contingency planning are available. (DIII.3a)
- I: Pharmacy Director describes how the organization manages its cash and cites examples of contingency planning.

 (DIII.3a)
- D&I: Pharmacy Director and/or Financial Manager describe and document the insurance coverage and discuss the rationale for the amounts. (DIII.3b)
- D: New Pharmacy product/service plan proposals include specified elements. (DIII.3c)
- I: Management team describes examples of recognition of interrelationship of finance, quality, product and service operations. (DIII.3d)

DII1.3

DIII.3	The Pharmacy Organization/Program has adequate and appropriate financial resources to meet its stated mission.
DIII.3a	The organization has a contingency plan and/or policies and procedures to adequately address cash or operating short falls that may impact the products and services it provides.
DIII.3b	Insurance coverage is maintained for the loss due to general liability, product liability, professional liability and work related injuries.
DIII.3c	New program, product or service planning and development occurs prior to implementation which includes analysis of effectiveness and profitability of the project.
DIII.3d	The management team's performance reflects an understanding of the interrelationship of finances, quality, product and service operations and long term viability of the organization.

LEGEND:

- **D DOCUMENTATION**
- I INTERVIEW
- O OBSERVATION
- S SURVEY

DIII.4

- O: Observation of the physical facility validates that elements 1-7 are in evidence and in conformance with state/federal requirements. (DIII.4a)
- D: Written policies specify elements 1-5. (DIII.4b)
- O: Work surfaces and equipment are cleaned and disinfected in compliance with pharmacy policy. (DIII.4b)

Note: Compounding environment includes walls and floors. (DIII.4b.2)

- D,I&O: Interview, observation and review of reference data validate that professional/community standards of practice are followed. (DIII.4c)
- O: Observation validates that sterile and non-sterile preparation areas are separate and adequate. (DIII.4d)
- D&O: Observation of injectible drug work areas and review of end product testing results validate compliance with the specifications designated in elements 1-3. (DIII.4e)

DⅢ.4 The Pharmacy organization has adequate and appropriate physical facilities to accomplish its stated mission.

- DIII.4a The Pharmacy organization has the necessary space, equipment and supplies for safe preparation, dispensing, storage and delivery of pharmaceuticals in compliance with state and federal requirements, and includes at a minimum:
 - 1) Preparation of sterile products for dispensing is within an ISO Class 5 environment
 - 2) Hot and cold running water with sink
 - 3) Walls, ceilings and floors made of non-porous cleanable surfaces
 - 4) Accurate balance and measuring devices
 - 5) Adequate ventilation and lighting
 - 6) Disposable hand drying towels
 - 7) Adequate storage facilities
 - (a) Parenteral compounding items stored to maintain integrity of aseptic environment
 - (b) Adequate refrigerator/freezer capacity to meet storage requirements for all refrigeration-required materials.
 - (c) Shelves and storage containers made of washable, non-porous materials, including non-use of corrugated cardboard/styrofoam
- DIII.4b The Pharmacy organization maintains adequate and clean compounding areas in compliance with its policies which specify:
 - 1) The adequacy of workspace per state regulations
 - Frequency, types of cleaning agents and procedures of how work surfaces, equipment and compounding environment are cleaned and disinfected
 - 3) Work surfaces are kept free of equipment, supplies, records and other material unrelated to the preparation of a given drug
 - 4) Certification of laminar flow hood per organizational policy and/or state/federal regulation
 - 5) Validation of cleaning and compounding practice including surface sampling, environmental air sampling and end product sterility testing for pyrogens.
- DIII.4c Storage of the final pharmaceutical product is in accordance with acceptable professional/community standards of practice which are supported by reference data, including temperature, light and length of time.
- DIII.4d Areas for compounding of sterile products are functionally separate from areas for the preparation of non-sterile products and are constructed to minimize opportunities for contamination of products.
- DIII.4e There are adequate work areas for the preparation and manipulation of injectable drugs, which includes the following:
 - Methods for inspecting ingredients and final products for the presence of inappropriate particulate matter or signs of deterioration or microbial contamination
 - 2) Use of laminar flow hoods
 - 3) Use of Class II Biological Safety Cabinets for the preparation of cytotoxic drugs

Revised: 3/13/06

LEGEND:

- **D DOCUMENTATION**
- I INTERVIEW
- O OBSERVATION
- S SURVEY

DIII.4 cont'd

- D: Documentation of semi-annual inspections and pre-filter changes as required is available. (DIII.4f)
- D: Certification reports from the most current three year period are available. (DIII.4f)
- I & O: Pharmacy personnel are knowledgeable of and use appropriate techniques when using a hood or cabinet. (DIII.4g).
- I&O: Interviews with staff and observation of practice confirms compliance with policies. (DIII.4h, DIII.4i, DIII.4j)
- D: Written policies specify elements 1-5. (DIII.4k)
- O: Products are shipped in compliance with the pharmacy's policy. (DIII.4k)
- O: Client service areas are private, clean, safe and in compliance with ADA regulations. (DIII.41)

Pharmacy CHAP, Inc. 2004/2005 Edition

Evidence Guidelines Page BB

- DIII.4f
- Laminar Flow Hoods and Class II Biological safety cabinets are inspected at least every six months and certified by an independent agency that they are operating according to specifications. Certification records are retained for a minimum of three years.
- DIII.4g
- Pharmacy personnel using a laminar flow hood or a Class II Biological safety cabinet use proper techniques consistent with professional standards of practice to ensure a continuous aseptic environment during the admixing of sterile pharmaceuticals.
- DIII.4h
- Preparation of injectables from sterile solutions includes the use of filters when removing solutions from ampules.
- DIII.4i
- Injectables prepared from non-sterile powders are:
 - 1) Dissolved in sterile solution for injection
 - 2) Filtered through a 0.2 micron filter.

- DIII.4j
- Respiratory medications prepared from non-sterile powders are prepared in an ISO 5 environment and are:
 - 1) Dissolved in sterile solution
 - 2) Filtered through a 0.2 micron filter
 - 3) Packaged under ISO 5 environment conditions
 - 4) Periodically end product tested

DIII.4k

Adequate shipping containers and shipping processes are used in accordance with regulations and manufacturers guidelines to assure drug stability and potency which includes the following:

- 1) Assurance of stability and potency of the products being shipped
- 2) Temperature control
- 3) Non-exposure to light
- 4) Non-exposure to contaminants
- 5) Packaging of medications in a tamper evident manner

DIII.41

The organization's physical facilities provide a safe environment for staff and clients and allow for the efficient provision of services.

- 1) Space and privacy are adequate for the services being provided
- Physical facilities and resources permit effective and efficient function of the personnel
- 3) Provisions are made to accommodate clients and staff with disabilities

LEGEND:

- **D DOCUMENTATION**
- I INTERVIEW
- O OBSERVATION
- S SURVEY

DIII.5

- D: External databases are available and used for comparison. (DIII.5a)
- D: Benchmark reports are available. (DIII.5b)

Note: Organizations may use internal standards, professional standards of practice guidelines, research findings or professional references to determine benchmarks.

Organizations may use multiple sites, divisions and/or professional reference data to benchmark against.

DIII.5	An effective and efficient management information system is utilized to ensure	
	accountability at all levels of the organization.	-

- DIII.5a When available, the organization uses external databases that provide information relevant to the organization's products and services and creates a basis for comparative analysis.
- DIII.5b The organization participates in a benchmarking system.
 - 1) Benchmark data are consistent with organizationally defined goals and objectives
 - 2) Benchmark collected data, when available, are measured against data from other organizations

DIV.

DIV.

THE PHARMACY ORGANIZATION IS POSITIONED FOR LONG TERM VIABILITY

LEGEND:

- **D DOCUMENTATION**
- I INTERVIEW
- O OBSERVATION
- S SURVEY

- D: The pharmacy operational plan is available. (DIV.1a)
- D: Governing Body meeting minutes document approval of the initial pharmacy operational plan and changes. (DIV.1b)

DIV.1	Operational planning reflects the Pharmacy's mission.	
DIV.1a	The planning process focuses on performance expectations and is consistent with organizational needs.	
DIV.1b	The written plan is developed, and the initial plan and changes are approved by the governing body.	

LEGEND:

- **D DOCUMENTATION**
- I INTERVIEW
- O OBSERVATION
- S SURVEY

- D: An annual evaluation of the pharmacy organization's program and operations is conducted. (DIV.2)
- I: Management describes the annual evaluation process and the way it is used for future planning for the organization. (DIV.2a)
- I: Management personnel describe how the complexity of the organization relates to data collection and utilization. (CIV.2b)
- D & I: Evidence exists that product and service pricing is routinely evaluated. (DIV.2c)
- D: The interrelationship between the pharmacy program evaluation and the overall organizational evaluation is evident when the pharmacy is part of a larger organization. (DIV.2d)

DIV.2	An annual systematic evaluation of major aspects of the Pharmacy Organization's program and operations provides the basis for future planning.
DIV.2a	Mechanisms are established in writing for the collection, dissemination and use of information for the purpose of management, quality improvement, planning and future evaluation purposes.
DIV.2b	Data appropriate to the complexity and scope of the Pharmacy organization is collected and monitored.
DIV.2c	Pricing of products and services is routinely evaluated.
DIV.2d	Results of the Pharmacy organization's evaluation findings are integrated into the corporate organization's report, if applicable.

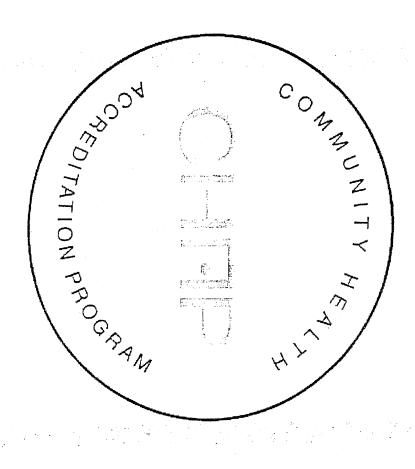
LEGEND:

- **D DOCUMENTATION**
- I INTERVIEW
- O OBSERVATION
- S SURVEY

O:	Innovations have been developed and implemented. (DIV.3)										
	•										

	·						
DIV.3	The Pharmacy Organization management team fosters innovation within the organization and brings strong leadership to industry-related activities.						
DIV.3a	A common and futuristic vision of the organization is established and sustained.						
	 A learning environment for all staff is promoted and supported Staff development is encouraged Governing body members have expertise specific to the enhancement of the 						
	organization's mission						
DIV.3b	An atmosphere of mutual respect permeates the organization throughout.						
	 Interaction between staff, administration and governing body is evident and is facilitated 						
DIV.3c	The organization has positioned itself to participate in public forums that shape health care policy and educate consumers.						
DIV.3d	The organization actively networks with other providers and provider organizations.						

PHARMACY SELF STUDY



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										r

2004/2005 Edition

INTRODUCTION TO PHARMACY SELF STUDY

The Community Health Accreditation Program, Inc. (CHAP) accreditation process is comprised of five steps:

- Submission of an application and application fee
- Submission of a signed contract accompanied by a pre-determined initial fee
- Submission of a completed Self- Study
- Comprehensive Site Visit by a team of professionals, the number of which is determined based on the size of the organization and complexity of services provided.
 - Review of the site visit report and determination of accreditation status by the CHAP Board of Review

The Self-Study process is completed by the organization seeking CHAP Accreditation:

- Prior to the initial site visit
- Prior to the first visit of a new accreditation cycle

What is the Self-Study?

organization in preparing for the on-site accreditation visit. The process involves a comprehensive internal self-assessment of the The Pharmacy Self-Study is a dynamic tool, used by pharmacy programs/services seeking CHAP accreditation that assists the organization's:

- Structure and Function
- Quality of Services and Products provided
- Resources: Human, Financial and Physical
- Long Term Viability

The Self-Study, 2004 Edition, has been revised to:

- Reflect the flow and content of Pharmacy Standards, 2004 Edition
- Apply to all pharmacy services and programs accredited by CHAP
- Promote the involvement of staff in the preparatory process to achieve accreditation by CHAP
 - Facilitate ease of use of the document by all levels of staff
- Infuse a new sense of organizational vitality, unity and sense of pride in completing a "job well done"
 - Assist the organization in determining a sense of readiness for the actual on-site visit

It is also anticipated that this new self-study format will:

- Simplify the preparatory process for all organizations seeking CHAP accreditation
- Eliminate duplication and redundancy when used in combination with the CORE 2004 Edition Self-Study
- Identify internal challenges and strategic issues to be addressed prior to the on-site CHAP Accreditation Site Visit

How does CHAP use the Self-Study?

inclusion of required attachments. The designated Site Visitor(s), assigned to conduct the actual site visit also receives a copy of the On receipt of the completed self-study, the CHAP office staff completes an internal audit of the document for completeness and the Self-Study document. The site visitor(s) studies and analyzes the document and attachments submitted in order to construct a plan that will facilitate the efficiency and effectiveness of all facets of the accreditation site visit process.

Additionally, after the completion of the on-site visit and development of the Site Visit Report, the Self-Study is available with the packet of information that is reviewed and acted upon by the Board of Review in making the final accreditation decision.

Suggestions for the Completion of the Self-Study

programs and/or departments. Selection of a chairperson, who assumes oversight responsibilities for the group, will assure adherence to established time frames and keep the committee focused on achieving a positive accreditation outcome. CHAP recommends that Study in order to avoid duplicative responses. CHAP also recommends that the CORE and Pharmacy Standards of Excellence and Sections I, II, III, and IV of the CORE Self-Study be completed prior to completing the companion sections in the Pharmacy Self-Evidence Guidelines be utilized with the self-study as the organization assesses itself for compliance with the CHAP Standards. CHAP recommends that a coordinating committee be appointed, comprised of representatives from each of the organization's

Reaching group consensus on implementing a working agenda

- Strategies for completion of the document
- Assignment of responsible parties
- Estimated time frames for completion of various components of the process
- Processes for monitoring specific activities
- Meeting schedules and progress reports
- Projected date for the submission of the completed Self-Study document
- Retrenchment as necessary and indicated

CHAP Accreditation staff are available and may be contacted by telephone or email for clarification of standards and questions as they arise during completion of the Self-Study.

Directions for Completion of the Pharmacy Self-Study Document

The CORE Standards and Self Study, 2004 Edition, are used in concert with the Pharmacy Standards and Self-Study, 2004 Edition. Complete the following documents of the Self-Study:

- 1) Contact Information Sheet
- 2) Organizational Data Sheets
 - 3) Organizational Questions4) Self-Study Spreadsheet
 - Self-Study Spreadsheet

1) Contact Information Sheet

Specify the name and informational data for the person to be contacted regarding the Self-Study and site visit information.

2) Organizational Data Sheets

Complete for the most current fiscal or calendar year period. These data are used by CHAP staff to assure appropriate staffing for the site visit and to prepare for the site visit.

3) Organizational Questions

compliance with the underlying principles in the CHAP standards. Site visitors will verify the information at the time of the site Be specific in your responses to the questions. These questions are intended to provide a snap-shot of the organization and its

4) Self-Study Spreadsheet

A spreadsheet format has been used to develop the revised self-study, affording the option of employing a computerized response. The written content follows that of the Pharmacy Standards of Excellence, 2004Edition, and details CHAP's four underlying principles:

- Structure and Function
- () Quality of Services and Products
- 3) Adequate Resources: Human, Financial and Physical
 -) Long Term Viability

PHARWACY

The eight (8) column format is defined as follows from left to right:

Column 1 CHAP Standards Alpha-numeric identifiers

Column 2 A description of the Underlying Principles and a duplication of the CHAP Pharmacy:

Standard Statements

Criterion Statements

• Elements of the Criterion (numeric identifier i.e., 1)

Sub elements of a Criterion (identified by use of an alpha letter, i.e., a)

Note: In rare instances, further enhancement of a sub-element is indicated by a (-) sign.

Columns 3&4 Identification of documents/information/activities that are either "In Place" or "Not In Place"

3 = "Yes" If in place, check appropriate box

4 = "No" If not in place, check appropriate box

"N/A" - Used to indicate that a Standard, Criterion, Element or Sub-element is not applicable to the Column 5

organization completing the Self-Study. If N/A, check appropriate box

attachment to the Self-Study. That designation will be included on the Self-Study by CHAP prior to being sent "A/R" Indicates those standards/criterion which must have a substantiating document submitted as an to your organization Column 6

"A/O" – Attachment Optional. An attachment that may be designated by CHAP or the organization seeking accreditation Column 7

Comment space for notations or points of clarification by the organization seeking accreditation by CHAP Column 8

Submission of Self-Study:

New York, NY 10006. Refer to the original CHAP contract letter for specific number of self-studies required to be submitted. Send the completed self-study with the required attachments to the CHAP Site Visit Coordinator, 39 Broadway, Suite 710,

Pharmacy Self Study (Contact Information)

For:		•
	Name of Organization	
Location:		
		The state of the s
Contact:		
Telenhone.		
i cichnone.		***************************************
E-mail:		
Submission Date:	ate:	
	Note: This should be the first nage of your Self Study	

Site Visitor Coordinator CHAP, Inc. 39 Broadway, Suite 710 New York, NY 10006 Mail to:

HARIVIA GV

ORGANIZATIONAL DATA SHEET PHARMACY

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(Only include positions not included in CORE)

Current Staffing:

	FTE Positions Budgeted*	Current FTEs*	Vacant Positions	Contract Staff
Executive Staff:				
Supervisory Staff:				
Support Staff (office/clerical):				
Sales Representatives Staff:				
Clinical Staff (RPh//RN/RT):				
Pharmacy Technician:				
Other Technicians:	The control of the co			
Delivery Personnel:				
Other:				

^{*} FTE = Full time equivalent (40 hour week = 2,080 hours per year)

ORGANIZATIONAL DATA SHEET (cont'd.) PHARMACY

Employee Turnover Rates:

Turnover rates (past fiscal year)	Pharmacy Staff	cy Staff
Positions	# of Individuals	Percent (%)
Administrative/management staff		
Supervisory staff		
Support Staff (Office/Clerical)		
Sales Representatives		
Clinical Staff (RPh/RN/RT)		
Pharmacy Technicians		
Other Technicians		
Delivery Personnel		
Other (specify)		
Total		

ORGANIZATIONAL DATA SHEET (

	PHARMACY PHARMACY	Y	
			4
evenue/ Expense:			
otal annual revenue:	↔.		÷
otal annual expense:	\$		·
surance Coverage Maintained:			
eneral liability:	\$	Malpractice:	S
irectors & officers liability	\$	Other	\$
Description of the second of t	7 1 11 11 1		

Products/Services Provided: (\lor Check all that apply)

Onen Door Pharmacu	1 4 1. 70 - IVJ IVJ	
Open Door 1 nathacy	Compounding of Non-Sterile Products	On-Site Delivery
Mail Order Pharmacy	Compounding of Sterile Products	Mailed Delivery
Infusion Pharmacy	IV Chemotherapy Drugs	Supplies for Infusion
Long Term Care Pharmacy	Parenteral/Enteral Nutrition	IV Pumps
Specialty Pharmacy (Specify Type)	IV Hydration Therapy	IV Poles
	IV Antibiotics	Other
	Blood Products	

ORGANIZATIONAL DATA SHEET (cont'd.) PHARMACY

Operating Sites/Locations:

			*.:			
Operating Sites & Locations	Funct	Functions Provided at Each Site/Location $$ all applicable	Each Site/I	Location √a	II applicab	le
List Corporate/Parent Site First.	Compounding	Compounding	Open	Mail-	On Site	Infusion
List all Other Sites/Locations/Hours of	Non-Sterile	Sterile	Door	Order	Delivery	Delivery Pharmacy
Operation & Distance from	Products	Products	Pharmacy	Pharmacy Pharmacy	Services	Services
Corporate/Parent Location,	•		Services	Services Services		
& Check all Applicable Functions for						
Each Site.						
					-	
						10

Specify other functions performed which are not listed:

HARNACY

ORGANIZATIONAL DATA SHEET (cont'd.) PHARMACY

Service Data:

Dates of last fiscal year:		
Total number unduplicated clients last fiscal year:		
Total number prescriptions filled last fiscal year:		
No. of Prescriptions filled per week day:		
No. of Prescriptions filled per weekend day:		
No. of on-site deliveries per day:		
Types of supplies provided:		
Volume of supplies provided per month:		
Size of Service Area (i.e., sq. miles):		
No. of States in Service Area:		
Names of States in Service Area:		
No. of Operational Sites/Locations:		
No. of unduplicated clients per therapy per year:	Anti-infective	TPN Inotropic
	Chelation	Chemotherapeutic
	Steroid	Hydration

2004/2005 Edition

Cath Care

xiv

ORGANIZATIONAL QUESTIONS

DI. STRUCTURE & FUNCTION OF THE PHARMACY ORGANIZATION

How is the pharmacy organization/program structured for administration? Explain how the role of the Pharmacy Program Director is implemented and how the Director fulfills the responsibilities for all professional services.

What is the composition of the Pharmacy organization's professional advisory committee? How are the members appointed?

Describe some relevant recommendations and/or outcomes resulting from professional advisory group meetings/activities this past year. Have ethical issues been identified within the past two years? How have they been handled within the organization? Cite an example.

D II. QUALITY OF SERVICES & PRODUCTS PROVIDED

How are the necessary services made available to clients at all times (24 hours a day, 7 days per week)? What is the plan for on-call coverage after hours, weekends and holidays? What mechanisms are in place to assure coordination of care with clients, client representatives and other health care professionals?

What is the process for assuring client identification prior to dispensing? 33

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resulted in identification of problems and improvement in performance. Cite two examples of significant changes made as a Describe the Pharmacy Program performance improvement plan. Describe how the findings from the monitoring result of the performance improvement efforts.

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D III. ADEQUATE RESOURCES

How are the skills and competencies of all staff providing client care/services assessed and assured?

How are the clinical competencies of pharmacy personnel using laminar flow hoods and/or Class II Biological safety cabinets assessed and assured?

- What is the organization doing to assure medication safety? Cite three examples. 6
- If the organization compounds sterile products, how is the organization assuring a safe end product?

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D IV. LONG TERM VIABILITY

If the Pharmacy Program is part of a larger organization, how is the program evaluation integrated into the overall organizational evaluation? How is the Pharmacy Program evaluated annually (by whom, frequency and parameters or criteria used)?

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	PHARMACY STANDARDS	IN PLACE	4CE			COMMENTS
		YES NO N/A	A/N	A/R	A/0	Constitution of the consti
UP I	STRUCTURE & FUNCTION					THE RESIDENCE OF THE PARTY OF THE CONTROL OF THE PARTY OF
	Awritten statement by the Pharmacy Organization identifies the scope of products and services provided to clients.			×		tradium memor as tills at the assessment of the second control of
DI.1a	DI.1a The scope of services statement is periodically reviewed, revised and approved by the	The state of the s				Appear agents a contract to the contract and the contract of t
	governing body but no less than every twelve (12) months.					
DI.1b	DI.1b The pharmacy's scope of services statement is made available upon request to clients,					THE TOTAL TO STATE OF THE PROPERTY OF THE TOTAL THE THE THE TOTAL
	referral sources and other interested parties.	-				
210	The Pharmacy Organization has the structure and functional mechanisms					
	necessary to accomplish its stated scope of services.		-			
D1.2a	D1.2a I he Pharmacy Organization has the legal authority to operate and is in compliance					
	with local, state and federal regulations.				PROCESS OF STREET, STR	Control of the Contro
	- 1	The same of the sa				ender som til dans i half til en stem stem ble som stem fra stem for det som en ende stem stem stem stem stem stem stem ste
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	- 1					Andrew Andrew Configuration and the Configuration and the Configuration and Configur
	4) d/b/a, Trade Name registration, if applicable					The state of the s
	5) Tax ID number	Manager of the State of the Sta		i		Charles Control of the Control of th
	6) Medicare & Medicaid provider numbers, where applicable			The second second	-	The second secon
	7) Specific county and state required authority					
DI.2b	DI.2b The Pharmacy Organization is required to prepare and maintain a current written					- American Computer Court of the Court of th
	disclosure statement signed by the chief executive, addressing applicable elements as					
	frequently as required by state regulations but no less frequently than every three					
	years.					
	1) Names and addresses of individuals or corporations having a combined direct					The second of the second secon
	or indirect ownership or controlling interest of 5% or more in the organization					
	2) Names and address of subcontractors in which the organization has a direct				4	
	or indirect ownership of 5% or more			1		
	3) Names and addresses of individuals, who are related as spouse, parent, child					Communication and the control of the
	- 1					
	4) Names and addresses of individuals in (1), (2), and (3) above with an					
	1					
	- 1					Characteristics of the Company of th
	6) The circumstances of any criminal offense conviction involving					The Companies for the president of the companies of the c
	Medicare/Medicaid programs on the part of any person(s) or organization(s)					
	in (1), (2) or (3) above and/or, on the part of any managing employee of the					
	1					
	 The dates of any changes in ownership or control during the previous twelve (12) months 					
	8) The dates of anticipated changes of ownership or control in the next twelve (12) months					
	(1 th) thousand					

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	PHARMACY STANDARDS	IN PI	IN PLACE	L		COMMENTS
		>	NO O	4 A/R	A/O	MATERIAL STREET, CONTRACTOR MATERIAL STREET, CONTRACTOR STREET, CONTRA
DI.2c	DI.2c An Advisory Committee of professionals is authorized by the governing body to advise the organization on policies and to evaluate the Pharmacy Program.	1				
	1) Responsibilities of the committee include establishment and annual review of pharmacy policies and participation in the annual evolution of the Dharmacy		4	1		
	2) Membership of the committee includes a physician, a pharmacist, a registered		1	;		
	nurse and at least one community representative who is not an employee			<u> </u>		
	3) Committee meeting minutes reflect the committee's fulfillment of its	1			-	The state of the s
	responsibilities					
	4) The Advisory Committee meets at least once annually.		-	-		The second secon
DI.2d	DI.2d Systems exist for obtaining and integrating the most current information into the	The second second second	-		-	Commence of the Commence of th
	professional practice to be used in planning, evaluation and decision making in all					
	aspects of the program		-			
7.0	Intra-organizational relationships of the Pharmacy Organization are					The second secon
	Oleaniy defined in writing					
DI.3a	DI.3a A current organizational chart illustrates the lines of authority and accountability for			1	1	Construct the management of the construction o
	all administrative, professional, technical, clinical and clerical personnel.			× —		
DI.3b	DI.3b The complexity of the Pharmacy organization's administrative structure is appropriate			-		And the following of the control of
	for efficient delivery of product and service.			-		
7.6	Authority and responsibility for the overall executive management of the	2016				COMPANY NEW TO A CONTROL OF THE CONT
	Pharmacy Organization is vested in qualified individuals.				*********	
DI.4a	DI.4a The Pharmacy Program Director is a graduate of a pharmacy program accredited by	-	<u> </u>	1	Property of the Co.	Resume
	the American Council of Pharmaceutical Education or has passed a Foreign Pharmacy					
	Graduate Equivalency Examination given by the National Association of Boards of			<		
	Pharmacy, is currently licensed as a Pharmacist in the state.					
DI.4b	DI.4b A qualified pharmacist with appropriate knowledge, expertise and experience is					Resulting Control of the Control of
	responsible for the management, direction, coordination and general supervision of all			<u>×</u>		
	professional services.					

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PHARMACY STANDARDS	IN PLACE	COMMENTS
	A A/R A/O	
DI.4c The Pharmacy Program Director is responsible for the following areas either directly or by clear delegation:	X X You	lob Description
Organizing and directing the Pharmacy program's operations to assure the availability of services and products provided		
2) Assuring adequate inventory of pharmaceuticals and supplies necessary to compound and dispense prescriptions appropriately, including periodic inspection for outdated products.		A CONTRACTOR CONTRACTO
3) Assuring all equipment utilized in the delivery of the organization's products and services is properly maintained		THE TRANSPORT OF THE PROPERTY
4) Assuring pharmacy services are provided in compliance with applicable laws, regulations, accreditation standards and ethical standards of practice		
5) Assuring adequate and appropriate staffing, including recruitment, orientation, in-service education and completion of annual performance appraisal		Commitmentum (parts) a commitment (commitmentum) and of the commitmentum (
6) Coordinating with other program areas and managers as appropriate, consistent with organizational structure		
7) Assuring the implementation of a pharmacy performance improvement program including evaluation of the home pharmacy program services		
8) Assuring Drug Control system consistent with policies and regulatory requirements		
9) Assuring Drug Dispensing system consistent with policies and regulatory requirements		
10) Assuring appropriate pharmacy supervision at all times	A CHARLEST CONTRACTOR OF THE PROPERTY OF THE P	
11) Assuring safe and appropriate service policies are developed and implemented		
DI.4d A qualified individual is designated in writing to act in the absence of the Pharmacy Director.		
DES. Phármacs policies and procedures reflect an emphasis on quality and the second entire of the Pharmacy program,		
and ensure client rights, and ethical standards of business and clinical practice.		
DI.5a Organizational literature, policies and procedures accurately reflect the current practice, current professional standards of service and scope of the Pharmacy program		
DI.5b Pharmacy Program administrative policies and procedures include:	A CONTRACTOR OF THE PARTY OF TH	
	X	
2) Capital Short-fall Contingency Plan 3) Pharmacy Reference Materials	and the state of t	
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PHARMACY STANDARDS	IN PLACE	LAC	ഥ			COMMENTS
	YES NO N/A	0		A/R	A/0	The second secon
DI.5c Pharmacy Program operational policies and procedures covering the scope of services						Andrew to the control of the control
provided are developed and include at a minimum:						
1) Storage of final pharmaceutical products		l l	1	<u> </u>		management of the second of th
2) First dose new drug administration		<u> </u>	-			Committee of the commit
3) Handling investigational drugs	-	1	<u>!</u> 	<u> </u>		Assistant of the control of the cont
4) Client/caregiver instruction		<u> </u>	<u> </u>	×		The second secon
5) Timely assessment of client eligibility and provision of service		<u> </u>				MATERIAL PROPERTY OF THE PROPE
6) Notification of referral source if client does not meet admission criteria		1			 	AMENDAMENTAL CONTROL OF THE PROPERTY OF THE PR
7) Delivery of services/products, as applicable		<u> </u>	<u> </u>			AND THE PROPERTY OF THE PROPER
8) Contents, dispensing and maintenance of infusion emergency kits		<u> </u>				The second second control of the second cont
		1		×		And the state of t
10) Selection, maintenance, use & control of infusion control devices for drug		<u> </u>				And the state of t
administration, as applicable						
11) Client identification confirmation				×		
12) Availability of latex-free supplies		-	-	-	-	THE RESERVE OF THE PROPERTY OF
13) Prescription labeling	-			×		The second secon
14) Materials/Inventory Management			-	1		THE SET OF THE PARTY OF T
15) Equipment cleaning, testing and tracking	The second second	1	<u> </u>	1	1	The second secon
16) After Hours Coverage	- Commence of the last	1	1	×		
17) Dispensing Records		<u> </u>	-	ı İ	i	THE PROPERTY OF THE PROPERTY O
18) Sterile Admixture Procedures for monitoring for medication errors, surface		 	1	 		
						
19) Preparation of injectables from sterile solutions		<u> </u>	<u> </u>	×		THE CONTROL OF THE CO
20) Preparation of injectables from non-sterile powders		<u> </u>	1	×	-	The state of the s
21) Preparation of respiratory drugs from non-sterile powders		-	1	×		The second secon
22) Clinical competency testing				×	İ	And interpretation to the following management of the following states of the
23) Competency testing of sterile product preparation			1	×		A STATE OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF T
24) Medication Error		1		×		THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE THEORY OF THE THE THEORY OF THE THE THE THEORY OF THE THE THE THEORY OF THE THEORY OF THE THEORY OF THE THEORY OF THE
25) Recall				<u> </u>		AND THE PROPERTY OF A STATE OF THE PROPERTY OF
DI.5d Clinical policies and procedures consistent with professional standards of practice are		1	<u> </u>			The state of the s
developed and include at a minimum the following:						
1) Client Assessment		<u> </u>		×		THE PROPERTY OF THE PROPERTY O
2) Medication Assessment			The second second			The second secon
3) Drug Profile Review		-			İ	
1 1			<u> </u>		Ī	
5) Development of a comprehensive care plan			-		-	The second secon
6) Clinical monitoring		-	-	 		
The formation and the state of				-	1	The second in the second secon

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PHARMACY STANDARDS	IN PLACE	_	COMMENTS
	A	A/R A/O	Annual community of the second
DI.5e Quality Improvement policies and procedures consistent with professional practice and		-	And the second s
regulatory mandates are developed and include at a minimum:			
1) Performance Improvement Plan		X	
2) Structure and routine maintenance of compounding areas			
3) Maintenance of Laminar Flow Hood			
4) Infection control, safety for preparation, dispensing, disposal of		· >	-
pharmaceuticals		٠	
DI.5f Policies identify when a physician or other qualified professional is required to be			
present for the administration of the first dose of a new drug to detect, monitor and			
respond to adverse drug reactions.	TO THE RESERVE OF THE PROPERTY	in the second	
Diso The Pharmacy Organization's business and clinical activities are			
conducted according to ethical standards.			
DI.6a A designated and qualified group of professionals/individuals address ethical issues	The state of the s		The second of the control of the con
relating to the business and clinical practices of the Pharmacy Organization. The		×	
issues include but are not limited to:			
1) Care delivery issues	And the second s		THE WORK OF THE PROPERTY OF TH
2) Product and service related issues	The state of the s		THE THE SHEET OF A CASE THE SHEET OF THE SHE
3) Billing and collecting issues			TO AN ADMINISTRATION OF THE PROPERTY OF THE PR
4) Medical necessity authorization issues			
5) Statistical data trending and tracking issues	CONTRACTOR CONTRACTOR	and the same of th	THE PROPERTY OF THE PROPERTY O
DI.6b Staff are knowledgeable about and carry out their responsibilities for providing	THE PARTY OF THE P		THE PROPERTY OF THE PROPERTY O
products and services in accordance with reimbursement and regulatory guidelines.			ę
			The second secon
DIREC The Pharmacy Organization contributes to the development and			•
		<u> </u>	The second secon
clients are fully informed and provide written consent.			
DI.7b Arrangements for student education experiences are formalized in written contracts or			-
agreements that specify the responsibilities of the Pharmacy organization and the			
educational institution.		-	des considere des el como de manda de des estado de como estado estado estado estado estado estado en estado de como estado estado estado en en estado en entre en estado en entre en estado en entre en estado en entre en entre en entre en entre en entre en entre en entre en entre en entre en entre en entre en entre en entre en entre en entre en entre en entre
DI.7c The Pharmacy organization demonstrates a positive attitude regarding research			
initiatives and considers requests for research in the area of pharmaceutical practice as			
	constitution of the second of		
DI.7d The Pharmacy organization encourages the publication of significant outcomes related			
to the management and practice of pharmacy.	The second secon		

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PHARMACY STANDARDS	IN PLACE	E)		COMMENTS
	YES NO N/A	N/A A/R	R A/O	dimensystativishing private frincesers of vanish for effects britished a destructual of entre a
				THE PROPERTY OF THE PROPERTY O
DITA Rate Scope of Services drives the activities of the Pharmacy Organization The and ensures public disclosure, client rights, and ethical standards of business and clinical practice.				
DII.1a The written public disclosure policy makes the Annual Report for Corporations, if applicable, available to the public on request.	and the state of t	×		
DII.1b A written Client Bill of Rights statement or other written admission documents are	***************************************			The second secon
provided to the client or the client's representative at the start of care or at the time of		_	×	
initiation of care and include the right to be fully informed of:				
1) Services and products being provided				The property of the property o
2) Organization's ownership and control				
3) Names and qualifications of individuals providing products and services		4	1	The second secon
And the right to:		-		The state of the s
4) Participate in one's own care	The state of the s			TO THE PROPERTY OF THE PROPERT
5) Continuity of products and services				The second and the second designation and a comparation for the second designation of the second
6) Education about the products and services to be provided	The second secon			THE RESIDENCE OF THE PROPERTY
7) Refuse part or all of the products and services to be provided				THE PROPERTY OF THE PROPERTY O
8) Receive products and services in a timely manner and in accordance with				THE PROPERTY OF THE PROPERTY O
organizational policy				
9) Be referred to another organization	- A AMPRIANCE OF THE PARTY OF T		<u> </u>	
10) Be free from abuse or exploitation of any kind	The state of the s			
11) Receive information, both verbal and written, in an understandable format.	The second state of the se			Observations and the professional and the professio
DII.1c The Client Bill of Rights is signed by the client or a representative of the client and	The same of the sa			A COLUMN TO THE PROPERTY OF TH
made a permanent part of the client's record.				
DII.1d For clients receiving open door pharmacy services, the Client Bill of Rights is posted			-	The state of the s
in a public area accessible to those clients.				-
DII.1e The Pharmacy organization's products and services are provided in accordance with				Amended and the second control of the second
the organization's scope of services.				
1) Statistical reports confirm that products and services are provided consistent				And the state of t
with the Pharmacy organization's scope of services.			-	
2) Staff at all levels are knowledgeable about and support the Pharmacy				
organization's mission and scope of services.				-

PHARMACY STANDARDS	IN PLACE		COMMENTS
	YES NO N/A	A/R	λ
1112 Pharmacy services are provided in accordance with organizational	The state of the s		The first of the control of the cont
include dispensing at the pharmacy site, transported delivery to			
DII 2al Pharmacy services include but are not limited to:			THE PROPERTY OF THE PROPERTY O
1) Interpretation and evaluation of the prescription order			The majorate is a control of the con
2) Drug product selection, compounding, dispensing, storage			
Distribution of drugs and devices	THE RESIDENCE OF THE PROPERTY		The second secon
4) Advising the prescriber and other health care professionals, the client and/or	MACAGINET CARD AND A CONTRACT OF THE ADMINISTRATION OF THE ADMINIS		
caregiver as to therapeutic actions, utilization and possible adverse reactions			-
and interactions in order to encourage a positive client outcome.			
DII.2b Pharmacy services are provided by or under the direction and supervision of a		-	
1) Professional pharmacy service is provided by a registered pharmacist and	Odnik kirik o kirik o	>	Job Description
include:		<	
(a) Overseeing the drug control system including:	THE RESIDENCE AND A STREET OF THE PARTY OF T		Transmission of the control of the c
1) Receipt of prescription drugs and prescription orders			Wilder of the control
2) Storage of medications	Manual Transport of the Company of t	İ	TO THE PROPERTY OF THE PROPERT
3) Packaging of medications	- commencer		
4) Preparation and dispensing of prescriptions	Manual State of the State of the State of State		Market of the second of the se
5) Labeling	CAMPA (FINANCIALA DE CAMPAGNICALA) (F. C. CAMPAGNICALA) (F. C. CAMPAGNICALA) (F. CAM		A ADMINISTRATION OF THE PROPERTY OF THE PROPER
	No. of the latter of the latte		The second control of the second control of
(b) Instruction/counseling clients and caregivers regarding specific dono	and the state of t		Andrew Company of the
(c) Providing information regarding the safe and appropriate use of		İ	
(d) Identifying appropriate outcomes of drug therapy	of societies are printed to the companies of the companie		THE PROPERTY OF THE PROPERTY O
(e) Consulting on drug therapy and coordinating with other health care	The commentation of the comments of the commen		
- 1			
(f) Monitoring and documenting ongoing drug therapy including the			
×1	Annual An		
- 1		-	
- 1	The state of the s		
3) Appropriateness of the dose, frequency and route of administration			
4) Adherence to drug regimen			THE PROPERTY OF THE PROPERTY O
5) Potential drug, food or diagnostic test interactions of disease	AND THE PROPERTY AND TH		
limitations to drug use			
6) Laboratory or clinical monitoring methods to detect drug			
- 1			
7) Preparing and maintaining clinical records			
(g) Prescribing activities consistent with state/federal regulations.	The second section of the second section is a second section of the second section sec		AND AND AND AND AND AND AND AND AND AND
Pharmacy Self Study	TOTAL STREET,		

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		YES 1	YES NO N/A	A/R	A/0	Amenda Van teal and designed of the education of the educ
2)	 Pharmacy technical services are provided by pharmacy technicians who have been trained for all tasks performed in compliance with state law, job description and organizational policy. 			×		Job Description
DII.2c The to cl	DII.2c The Pharmacy Program provides pharmaceutical care, related supplies and equipment to clients.					A CONTRACTOR OF THE PROPERTY O
DII.2d Deli	DII.2d Delivery services are provided directly or by arrangement in compliance with laws and regulations and include:			×		Job Description
1	 Safe and clean transport of pharmaceuticals and supplies to and from client homes/designated sites 			1		
2)	1 1					A CONTRACT OF THE PROPERTY OF
3)	1					THE OWNER THE PROPERTY OF THE
(+) Setting up equipment in client homes, if applicable					
DII.2e The	DII.2e The organization has a process in place for assuring the availability of drug and supplies to clients in their designated sites not available from the organization.			×		
DII.2f The			<u> </u>		The same and the s	The second secon
toc				<u>×</u>		
	Clinical services and products are accessible and available to clients on an entergency basis 24 hours a day, 7 days a week		1	1		Commission control to the control of
DII.3a The	DII.3a The Pharmacy Organization is accessible and responsive to the needs of Clients during	1		<u> </u>	-	TO THE TOTAL THE
nou	normal work hours and after hours which includes:			and the same of th	THE PERSON NAMED IN	
	-	-		1		The second secon
2)			-			
3)) Product and service delivery prior to scheduled use	i	1		N AND AND AND AND AND AND AND AND AND AN	
DII.3b The	DII.3b There is a plan for on-call coverage for after hours, weekends and holidays.	The second second second	-	×	1	
DII.3c Clic	DII.3c Chents are informed of the process for accessing service during normal work hours and after hours.			<u>×</u>		
DII.3d Wn	DII.3d Written contingency plans delineate protocols for prioritizing delivery of product and					The state of the s
ser	services to clients including:				-	
	1) Disaster preparedness					
2)	.) Inclement weather events					
3)) Unexpected critical staffing deficits	- Milde Hann decides				
	The Pharmacy Organization admits clients whose service needs can be					
i de	met and ensures confinulty of care service through coordination of client service.	a conserv				
DII.4a Cli	DII.4a Clients are admitted to service and continued on service, based on the reasonable expectation that their needs can adequately and safely be met by the program				The state of the s	
Tun			-	4		THE PROPERTY OF THE PROPERTY O

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THANKIACI SIANDAKDS	VES NO N/A A/R	R A/O	A THE LEGISLA CONTRACTOR AND A CONTRACTOR OF THE
DII.4b A pharmacist assumes responsibility for planning, implementing therapy, evaluating the outcomes of therapy provided as applicable and documenting in the client record.			
11. O 7110.	The second secon	***************************************	
DILAC Care is coordinated for each client by the pharmacist and includes at a minimum: 1) Periodic verbal, telephone or electronic communication with other professionals	4		- Color Colo
involved in the care of the client	TORNAL COMMENT TORNAL COMMENT		
2) Timely documentation of the coordination of care activities			
3) Involvement of the client/client representative when indicated			
DII.4d For other than open door pharmacies, care coordination includes elements 1-3 of			
DII.4c plus the following additional components:	The second secon	-	
1) Initial assessment of the client, family and, if applicable, the home environment	and the second of the second o	The state of the s	The matter of the first of the second of the
2) Development of a plan of care	The state of the s		
3) Determination of expected outcomes			
4) Appropriate referral and follow up			
5) Implementation of the care plan			
6) Ongoing evaluation			
7) Plan of termination of care			THE PROPERTY OF THE PROPERTY O
DII.4e The pharmacist works collaboratively with other health care professionals to assure			Company of the compan
coordination of care.			
1) The client drug profile information is available to professionals participating			
in the care of the client:	The state of the s		
a) at a minimum, during operating hours for all pharmacies	The state of the s	100	
b) at all times, including after hours for infusion pharmacies	And the second s		
2) The delivery of medications, equipment, and supplies is coordinated with			
other professionals involved with the care of the client to ensure that proper			
products and supplies are available when needed.	VENEZA ENTREMENTAL EN TRANSPORTE EN TRANSPOR		emplementation of the state of the control of the state o
assessments, physician oversight, dispensing and client training.			
DII.5a An initial client assessment is made by the pharmacist prior to dispensing which			
includes at a minimum:		1	
- 1			AMERICAN PROPERTY OF THE PROPE
			And the second s
4) Physician name, telephone number	The same of the sa		

PHARMACY STANDARDS	IN PLACE	ACE.		_	COMMENTS
	VES	NO N/A	A/R	A/0	AND THE LANGE THE PROPERTY OF
DII 5b For infusion and long term care pharmacies an initial client assessment is made by the)	The second of the second secon
phormacoist prior to discussing which includes a summer of a for III & a large the			>		
-			< −		. :
1) Chief Complaint/Medical history/Diagnosis				Table 1 Table 1	THE PROPERTY OF COMMENT OF THE PROPERTY OF THE
					The state of the s
	A sept a season management				The Second Control Con
5) Citeti IIIIectioni, Sensinvities obtained as available		-			The second section is the second section in the second section in the second section is the second section in the second section in the second section is the second section in the second section in the second section is the second section in the second section in the second section is the second section in the second section in the second section is the second section in the second section in the second section is the second section in the second section in the second section is the second section in the second section in the second section is the second section in the second section in the second section is the second section in the second section in the second section is the second section in the second section is the second section in the second section in the second section is the second section in the second section in the second section is the second section in the second section in the second section is the second section in the second section in the second section is the second section in the second section in the second section is the second section in the section is the second section in the section is the second section in the section is the second section in the section is the section in the section in the section is the section in the section is the section in th
4) Significant Lab Results					THE RESIDENCE OF THE PROPERTY
DII.5c A medication assessment is made by the pharmacist prior to dispensing which includes			;		
at a minimum:			×		
1) Potential drug interaction	The state of the s				The second secon
2) Potential for poly-pharmacy	The same of the sa			1	THE PARTY OF THE P
3) Appropriate dose and frequency	***************************************		La regard to cause		AND THE RESTORAGE OF THE PROPERTY OF THE PROPE
4) Appropriate time of administration					THE CONTROL OF THE CO
5) Appropriate route and method of administration	***************************************				The second control of the second control of
1		- AND LOCAL PROPERTY AND LOCAL P		The state of the s	- CHARGE AND AND AND AND AND AND AND AND AND AND
TATE STATE OF THE	The second second second		-		A Margani nga Prisina A Marana angang manana na a ana i mangang manana na magang mangang ngang ngang ngang ngang
DILOG Pharmaceuticals are dispensed according to the prescription of a physician or					•
physician designee legally authorized to prescribe in compliance with state regulation:					
	Annual Control of the			-	The state of the s
1) Written, verbal or faxed prescriptions are available to the pharmacist before					
- 1					
2) Verbal orders taken from a physician or physician designee are recorded and	-				THE PROPERTY OF THE PROPERTY O
signed by the pharmacist prior to filling the medication order					
DII.5e All pharmaceutical products dispensed to clients are appropriately labeled according to		-			Million and American proper regular to the control of the control
state and federal regulations and, at a minimum, include:					24.
1) Name, address and telephone number of the pharmacy			***************************************	-	
2) Date the prescription was dispensed	***************************************		Think I Think to	-	THE RESERVE OF THE PARTY OF THE
3) Expiration date of the medication			-		
4) Pharmacy's prescription number					
5) Client's full name	The party of the p	1			THE RESERVED TO SERVED THE PROPERTY OF THE PRO
6) Name of the drug, brand, strength, if applicable, and the amount dispensed				-	
7) Directions for use		-		A THE PERSON NAMED IN COLUMN 2	COMMANDED CONTRACTOR (CONTRACTOR CONTRACTOR
8) Prescriber's name	-				
9) Other pertinent information or cautionary labels					
10) Rate, route and method of administration	market conjustment			-	
11) For IV mixture drugs, rate of administration and expiration date of the fluid				Victoria in Lab	

PHARMACY STANDARDS	IN PLACE	COMMENTS
	YES NO N/A A/R A/O	
DII.5f A comprehensive plan of care is developed by infusion pharmacies which includes:		I Sample
1) Establishment of Therapy Specific Goals	The state of the s	CONTRACTOR OF THE CONTRACTOR O
2) Determination of Expected Outcomes		THE RESERVE OF THE PROPERTY OF
3) Determination of Educational Needs		
4) Establishment of Monitoring Plan		THE RESERVE OF THE PROPERTY OF
5) Determination of Achievement of Goals/Outcomes		And the second of the second o
6) Periodic Review by Prescribing Physician	THE PERSON NAMED IN COLUMN TWO IS NOT THE PERSON NAMED IN COLUMN TWO I	THE PROPERTY OF THE PROPERTY O
DII.5g Client identification is confirmed prior to dispensing.	X	
DII.5h For pharmacy infusion services, there are policies and procedures for emergency		TO THE PROPERTY OF THE PROPERT
situations including, ordering of emergency kits with appropriate drugs by the	×	
physician and placement of these kits in the client's home, where appropriate.		
DII.51 Drug information and instructional materials for administration are provided to the		Among and a second of the composition of the compos
client or client caregiver at the time of dispensing.		
DII.5] Client training/education in self-administration is provided upon initiation of therapy,	apy,	The second of th
1000		
DIR.6 Clientrecords are maintained for each client and are utilized as a tool for	l for	
coordination of services, as legal documentation of products and services	i ces	
firowided and as a basis for billing and reimbursement procedures.		
DII.6a Adequate and appropriate pharmacy records are maintained		The second section of the second second second second section of the second section of the second se
1) Drug profiles are maintained for all clients and include the following		The first of the f
information:		
(a) Name, gender, birth date and weight (when appropriate)	A CONTRACT AND AND A CONTRACT AND A	THE THE STATE OF THE PROPERTY
(b) Address and client identification		
(c) Allergies or sensitivities		
(d) Diagnosis		THE PROPERTY OF THE PROPERTY O
(e) Current drug regimen		
(f) Dosages		
(g) Relevant clinical information regarding drug therapy		
(b) Physician's name		THE PROPERTY OF THE PROPERTY O

ONE THINT ES AN TIME THE	00 1 20 141	
LIANIMACI STANDANDS	VES NO N/A A/R A/O	COMMENTS
2) Dispensing records are maintained for pharmaceuticals which include:		The AND AND AND AND AND AND AND AND AND AND
(a) Client's identification, name and address	The state of the s	
(b) Name of medication	Management of the control of the con	A DESCRIPTION OF THE PROPERTY
(c) Strength and dosage form	The state of the s	The service of the se
(d) Quantity dispensed	The state of the s	THE PROPERTY OF THE PROPERTY O
(e) Physician's name	TOTAL STATE OF THE	TO A CHARLES AND ADDRESS OF THE PARTY OF THE
(f) Dispensing pharmacist/technician identification	The second contract of the second contract of	THE PROPERTY OF THE PROPERTY O
(g) Prescription number	THE PROPERTY AND A THE PROPERTY AND A STREET	THE PARTY WAS AND THE PARTY WAS A CONTROL OF THE
(h) Date dispensed	The second section of the section of th	TO ARTHUR TO THE CONTROL OF THE CONT
(i) Directions for use	The state of the s	THE RESIDENCE OF THE PROPERTY
(j) Expiration date	The second secon	THE SECTION OF THE SE
(k) Number of refills authorized	And the state of t	AND THE RESIDENCE OF THE PROPERTY OF THE PROPE
3) Dispensing records for other than open door pharmacies are maintained for	(A rich and Armen and Arme	The second control of the second control of
pharmaceuticals which include elements a-k of DII.6a2 plus the following:		
(a) Lot number(s) of drugs	After the first of the comments of the first	THE PROPERTY OF THE PROPERTY O
(b) Date of the addition(s) to intravenous admixture drugs	The second secon	TOTAL TOTAL TRANSPORTED TO THE PROPERTY OF THE
(c) Special compounding instructions as applicable	THE CONTRACTOR OF THE CONTRACT	And the second s
(d) Documentation of verification procedures	According to the control of the cont	The second secon
4) Controlled substance records are maintained in accordance with state, federal	Company of the Compan	
and practice regulations documenting that:		
(a) A controlled substance inventory is performed in compliance with state	The same of the sa	
or federal regulation.		
(b) The pharmacist in charge is held accountable for the exact count of		THE PROPERTY OF THE PROPERTY O
- 1		
(c) The pharmacist in charge is held accountable for an approximate count		
of Schedule III, IV, and V pharmaceuticals.	And the second s	
DII.6b Automated clinical record systems ensure consistent and ongoing protection of data.		
1) Written policy describes signature authentication in accordance with	A THE COLUMN TWO COLUMN TO THE COLUMN TWO CO	THE PROPERTY OF THE PROPERTY O
- 1	<u>×</u>	
- 1	The state of the s	THE TOTAL PARTY OF THE PARTY OF
3) Individual and protected access codes are assigned to individuals designated		AND THE REAL PROPERTY OF THE P
- 1		
4) Automated programs designate and control areas of access by authorized		
- 1	The party of the property of the second seco	general de la companya del companya del companya de la companya de
- 1	Charles and the contract of th	The control of the co
- 1		
- 1	AND THE PROPERTY AND THE PROPERTY OF THE PROPE	THE THE THE PARTY OF THE PARTY
8) A system for validation of inputted data is in place	Contraction of the Contraction o	
9) An automated system for backup and storage of data is controlled, and the		
data is stored in a safe environmental place.	The second secon	

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	PHARMACY STANDARDS	IN PLACE	ACE			COMMENTS
		YES N	YES NO N/A	A/R	A/0	THE THE PARTY OF T
	DILT The adequacy, appropriateness, effectiveness and outcomes of products, services and supplies provided are routinely assessed.		-			
DII.7a	DII.7a The Pharmacy Program has a formalized quality improvement program which is					The state of the s
	designed to:					
	1) Identify desired outcomes					The state of the s
	2) Identify strategic and at-risk activities					
	3) Establish monitoring parameters for these activities	The state of the s				COMPANY OF THE PROPERTY OF THE
	4) Establish minimal standards or criteria to be met	-				
	5) Describe methods used to improve the quality of service and to achieve the	No. of Concession, Name of Street, or other party of the Concession, Name of Street, or other pa			ACCIONATA LA RANGE MANAGEMENT DE LA RANGE MANAGEMENT DE LA RAGIONALISMA DE LA RAGIONALISM	
AL III	ucsucd outcourts. The Pharmany Program has a viritian norformance.			and the same of th	The state of the s	The second secon
7	carried and a manner of a regional mas a watered performance improvement plan which includes:			×	······································	
	1) Description of specific monitoring and evaluation activities				A THE PARTY OF THE	WHERE IT AND THE THE THE THE THE THE THE THE THE THE
	2) Specification of how results are to be reported and evaluated	The second secon	-		Andrew Control of the	THE THE THE TOTAL OF THE THE THE THE THE THE THE THE THE THE
	3) Identification of appropriate follow-up mechanisms when thresholds are					
	exceeded	1		-	- Constant	
	4) Delineation of individual responsibilities for each aspect of the program.					Total and the state of the stat
DII.7c	DII.7c The Pharmacy Program's performance improvement program includes but is not limited to:	The same statement of the same statement of	-	Topic and the second second		restrict the state of the state
	1) Monitoring for medication errors	The same of the sa	***************************************		And residence of the second of	CHECKET AND THE COLUMN TO THE A PROPERTY CONTRACTOR OF THE CONTRACTOR OF THE COLUMN THE
	2) Monitoring and analysis of the findings from surface testing, environmental					AND AND AND AND AND AND AND AND AND AND
	air sampling and end product testing that includes sterility and pyrogens.				·	
DII.7d	DII.7d Staff orientation and in-service programs integrate a focus on quality.	The state of the s	1		Commence of the commence of th	And the second s
DII.7e	DII.7e The Pharmacy Program's performance improvement plan is integrated into the overall	a description of the second of				
	lorganizational quainty milprovement plan, as applicable.					

	PHARMACY STANDARDS	IN PLACE	CE		COMMENTS
		YES NO	NO N/A A/R	R A/O	The conference of the control of the first o
8110	The realth and well being of employees and clients is promoted and	Company of the Compan			A CANADA MANAGAMBAN AND AND AND AND AND AND AND AND AND A
	maintained through education and implementation of current infection ranting milities and safety measures				
DII.8a	DII.8a Infection control and safety measures for the preparation, dispensing and disposal of		***************************************	The second secon	A proprietable described for the color of the proprietable stage is the stage to the stage and the proprietable stage of the stage of t
	pharmaceuticals include but are not limited to:		×		
	1) Observation of standard precautions				The second secon
	2) Adequate hand hygiene/hand washing			California and and and and and and and and and an	
	3) Procedures for preventing exposure to blood borne pathogens			Opening the state of the state	
	4) Glove, gown and eye shield use while compounding hazardous products and	To company the company of the compan	CONTRACTOR OF STREET,		THE RESIDENCE PROPERTY OF THE
	chemotherapeutic substances				
	5) Use of aseptic technique	-		And Annually of Street, Street	The second control of the second control of
	6) Appropriate use of particulate and/or bacterial filtration	The state of the s	Mary hade - Advance - Account	Andreas of the state of the sta	
	7) Hood decontamination practices	-	- American de la companion de	The second secon	
	8) Venting of the laminar flow hood outside the building or use of a Class II		Total Control Control		AMERICAN CONTRACTOR OF THE PROPERTY OF THE PRO
	Biological Safety Cabinet when compounding cytotoxic drugs				
	9) Proper disposal of needles used in the preparation of pharmaceuticals done				THE PARTY OF THE P
	by disposing of needles in a tamper proof, puncture resistant container				
	10) Proper disposal for hazardous waste products			-	
DII.8b	DII.8b When applicable, the home environment is assessed to evaluate potential safety				en menen menen den de de de de de de de de de de de de de
	hazards and to instruct the client and/or those associated with the care of the client				•
	about safety precautions. The assessment and client teaching is documented in the				
	client's record.				
DII.8c	DII.8c Disposal of outdated drugs, controlled substances or hazardous wastes is documented and conforms to state and federal requirements.		<u>×</u>		
	1) Controlled substances are returned to the Drug Enforcement Administration if			And the second s	AND THE PROPERTY OF THE PROPER
	required. Documentation of the disposal of controlled substances on site is				44
	witnessed by two individuals and includes the amount and type of the drug.				
	2) Material Safety Data Information is kept in the pharmacy and identifies			The state of the s	
	3) Clients are instructed regarding the proper disposal of hazardone products in			The second secon	
	4) Records are maintained, as required			The second secon	
DII.8d	When clients and caregivers prepare sterile preparations in the home, they are	No. of Concession, Name of		and the second s	
	instructed verbally and in writing regarding safeguards against microbial		×		
	contamination, including, but not limited to the following:	The state of the s			
					AND THE RESERVE AND THE PROPERTY OF THE PROPER
,			Mana, 17 year	The state of the s	
	3) Duration and stability of the prepared solution			Andrews of the control of the contro	
	Constitution of the second of	James Learning		The in-	AMERICAN PROCESS AND ADMINISTRATION AND ALL AND ADMINISTRATION ADMINISTRATION ADMINISTRATION AND ADMINISTRATION ADMINISTRATION ADMINISTRATION ADMINISTRATION ADMINISTRATION ADMINISTRATION ADMINISTRATION ADMINISTRATION ADMINISTRATION ADMINISTRATION ADMINISTRATIO

	PHARMACY STANDARDS	INPI	IN PLACE	L	_	COMMENTS	
		YES NO N/A	O N/A	A/R	8/A/O	Average a vertical a total de transfer de l'average à l'average des averages des la vertical de l'average de	and the first charge of the company
DII.8e	DII.8e Infection control and safety control policies are established and implemented for the equipment/delivery service, including:	THE REAL PROPERTY AND ADDRESS OF THE PARTY AND		×		The same of the sa	
	1) Maintenance, testing and repair of equipment according to manufacturer's	The same of the sa	<u> </u>		-		
	guidelines						
	2) Cleaning and storage of reusable equipment between usage	The state of the s		,		of control delication to the control of the control	The commence on the case of th
	3) Inspection of equipment prior to delivery.				-	TO THE PROPERTY OF THE PROPERT	Company of the contract of the contract of the company of the contract of the
DII.8f	DII.8f The Pharmacy Program that prepares compounded sterile products conducts the	-			-	THE TRANSPORT OF THE PROPERTY	Compression of the compression o
	1) Routine disinfection and quality testing of direct compounding environment				1	The same that the same supplies the same of the same states of the sam	A STATE OF THE PERSON NAMED IN COMPANY OF THE PERSON NAMED IN CO.
	2) Visual confirmation of personnel processes regarding gowning, and other					A STATE OF THE PROPERTY OF THE	Andrew Control of the control of the
	infection control/safety measures						
	3) Review of orders and packages of ingredients to assure correct identity and	And a second law of			1	The formulation of the control of th	And share of the state of the s
	amounts of ingredients						
	4) Visual inspection of compounding sterile products	and the same of th		i	Per Jackson	The state of the s	
	5) Media-fill test procedure performed at least annually for each person			1	1	The first of the state of the s	*
0110	Clentcomplaints and concerns are responded to and resolved in a fimely	-	1	1	-	en des la fina e l'ambient de la company de l'ambient de	
DII.9a	DII.9a The complaint process includes:	TO THE REAL PROPERTY AND ADDRESS OF THE PERSON ADDRESS OF THE PERSON AND ADDRESS OF THE PERSON ADDRESS OF THE PERSON ADDRESS OF THE PERSON ADDRESS OF THE PERSON ADDRESS OF THE PERSON ADDRESS OF THE PERSON ADDRESS OF THE PERSON		1	1	the material and appropriate control of the control	The state of the s
	1) Designation of the individual(s) responsible for responding to the complaint			-	-	The first time of the control of the	en eller ette ett etteratione / mentje je kanggjen ette
	2) Procedures for responding to complaints			1	-	The control of the second of the control of the second of	the former of the party of the
	3) Time frame for responding to complaints			-		And the state of t	The A. Charle of the State presented representation of the same and
	4) Assurance that corrective action is taken as appropriate	-	1			TO DESIGN AND THE PARTY AND ADMINISTRATION OF THE PARTY ADMINISTRATION OF THE PARTY AND ADMINISTRATION OF THE PARTY AND ADMINI	***************************************
	5) Assurance that client and family rights are protected			1	-	Commence of the comment of the comme	e de composito de conferencia de la composito
	6) Follow-up activities		<u> </u>			Committee of the state of the s	to considerable to the a first desirence brought and the
	7) Resolution of the complaint		<u> </u>			The state of the s	Mary In addition to the latest th
	8) Complainant is informed of the outcome		<u> </u>	1		THE PROPERTY OF THE PROPERTY O	Actual street databases and treet successional databases in the second database.
	9) Trending of justified complaints	-		<u> </u>		A description of the state of t	THE PERSON NAMED IN COLUMN TWO PERSONS AND ADDRESS OF THE PERSON NAMED IN COLUMN TWO PERSONS AND ADDRESS OF THE PERSON NAMED IN COLUMN TWO PERSONS AND ADDRESS OF THE PERSON NAMED IN COLUMN TWO PERSONS AND ADDRESS OF THE PERSON NAMED IN COLUMN TWO PERSON NAMED IN COLUMN TRANSPORT NAMED IN COLUMN TWO PERSON NAMED IN COLUMN TWO PERSON NAMED IN COLUMN TWO PERSON NAMED IN COLUMN TWO PERSON NAMED IN CO

	PHARMACY STANDABNS	IN DI	IN DI ACE			Committee of a committee of the policy of the committee o
	CONDAIN TOTAL	VECN	NO NA			COINTREAM S
III dili	ADPOUATE PECOLIBORS HILMAN BINANCIAL & DUVELCAL	21	D NA	A/K	D/A/	And a compact space of any for a compact control of the compact cont
*	ADECUALE RESOURCES - HUMAIN, FINAINCIAL & PHYSICAL	The state of the s	-	-	A comment of the last	Control of a commence of the following of the following of the following of the control of the following of
	The Pharmacy organization has adequate and appropriate human resources to meet workload demands.					
DIII 15	Ctoffing midalines are devialanced and implemented to advantable, many well-lead		-	-		Andrews - Organization - Extensive the Company of t
DIII.18	Diff. 14 Stating guideimes are developed and mipremented to adequately meet workload demand.			×		
DIII.116	DIII.1b Oualified personnel are recruited and retained. Documentation is found in the	***************************************	1		İ	THE PROPERTY OF THE PROPERTY O
	personnel files, health files or administration files of the following:					<u> </u>
	1) Budgets allocate sufficient funds to ensure staffing at all levels and are			1		The second control of the second control of
	maintained to adequately meet workload demands					
	2) Positions, new and vacant, are filled on a timely basis to sustain	-	-			Community and the Control of the Con
	- 1					
	3) Clinical staff show evidence of graduation from colleges approved or		1		Total dramam.	And the state of t
	accredited by their respective professional organization					
	- 1					THE PROPERTY OF THE PROPERTY O
	5) Clinical staff show evidence of continuing education when required			<u> </u>		The state of the s
	6) Pharmacy technicians show evidence of certification, or have evidence of			1	İ	The formal country of the formal and the first of the formal and t
	adequate training, for all tasks performed in conformance with applicable laws					
	7) Delivery personnel, when utilized, have a clean driving record and maintain a		The same of the sa			The state of the s
	current driver's license					
	8) Delivery personnel, when utilized, show evidence of adequate training for all			1	1	The second designation of the control of the contro
	- 1					-
	9) Professional & technical personnel show evidence that professional skills are					THE PARTY OF THE P
	assessed and updated			-		The state of the s
	10) Compounding personnel show evidence of skills, training, and competency					
mu	testing to perform and document compounding duties.			-		THE COLUMN TO A SECURE AND A SECURE ASSESSMENT AS A SECURE ASSESSMENT AS A SECURE ASSESSMENT AS A SECURE ASSESSMENT AS A SECURE ASSESSMENT AS A SECURE ASSESSMENT AS A SECURE ASSESSMENT AS A SECURE ASSESSMENT AS A SECURE ASSESSMENT AS A SECURE ASSESSMENT AS A SECURE ASSESSMENT AS A SECURE ASSESSMENT AS A SECURE ASSESSMENT AS A SECURE AS A SE
DIII.10	DILLIC CHIRICAL COMPETERICY EVALUATIONS ARE PETTORMED TO ASSESS EMPLOYEE DASIC SKILL levels for all staff providing client care/services:					
	1) At time of hire		-			
	2) Annually, thereafter		To Vianantana			THE PROPERTY OF THE PROPERTY O
DIII.1d	DIII.1d Clinical competency evaluations of pharmacy personnel who use laminar flow hoods					STATE OF THE PROPERTY OF THE P
	and/or Class II Biological safety cabinets are conducted at time of hire and annually					
	351					
	1) Written test to verify employee's understanding of the concepts of aseptic					
	i	and completely				
	- 1			į		
	- 1					
	- 1		-	-		
	5) Observation of cleaning, testing and calibration of compounding equipment					

	PHARMACY STANDARDS	IN PLACE	CE	-	COMMENTS
		YES NO	A	A/R A	A/0
DIII.1e	DIII.1e The orientation plan addresses at a minimum:		-		
	- 1			1	
	2) Organizational Chart				A STATE OF THE PROPERTY OF THE
	3) Lines of authority and responsibility	-			A COMPANY OF THE MAN AND THE PARTY OF THE PA
	4) Job related responsibilities (job description)		<u> </u>		
	5) Human Resources policies/conditions of employment				The state of the s
DIII.1f	Ther				TO THE PROPERTY OF THE PROPERT
: :	1) Professional Pharmacy services are provided by or under the direction and			-	
	- 1				
	2) Staffing ratios of pharmacists to pharmacy technicians are in compliance with				
	state regulations.				
DIII.1g	DIII.1g Pharmacists show evidence of participation in formal in-service programs required by			1	THE PROPERTY OF THE PROPERTY O
	state regulation and organization policy.				
DIII.1h	DIII.1h The organization provides a minimum of one medication safety in-service annually		:		A MARKATER CONTROL OF THE CONTROL OF MICE AND A SECTION OF THE CONTROL OF THE CON
	Rormal Written contracts and agreements with other organizations and/or	Manual Control of the		i	CHARLES OF THE PROPERTY OF THE
	individuals for the provision of pharmacy products and services to				
	pharmacy organization clients defail snecific resnonsibilities of the narties				
DIII.2a	DIII.2a Formal written contracts and agreements with other organizations and/or individuals			The same of the sa	One Prototyne
	for provision of pharmacy services includes specific responsibilities as defined in			>	
	CIII.2a-b and, in addition, the following specific responsibilities:			4	
	1) Which organization has the authority to accept and terminate client services				
	2) Services provided under contract must be in compliance with professional		-		And the state of t
	- 1				
	3) The manner, in which products and services will be controlled, coordinated				THE RESIDENCE OF THE PROPERTY
	and evaluated				
אני ווויח	1 1		İ	1	
J	Thannacy Standards and are in compliance with CIII 2a-b. DIII 2a and in addition			×	One Prototype
	include the provisions for:			4	
	1) Who is responsible for teaching the client about pharmaceuticals				
	2) Assurance that personnel meet the pharmacy program's educational and				
	training requirements				
	- 1				THE PROPERTY OF THE PROPERTY O
	1				William Colonia and the Coloni
	5) Hours when pharmaceutical services are available to the client, including				
	Altangements for services during "off hours"	1		-	
	1	-		_	

PHARMACY STANDARDS		INP	IN PLACE	-	-	COMMENTS
		YES	YES NO N/A	4 A/R	R A/0	
7) Responsibilities of contractor and contractee, including:						TRACKY (Americans and Americans
(a) Who assesses the need for pharmaceuticals				<u> </u>		Control for the second of the
(b) Who contacts the pharmacy	AMENDA VARIANTE ANTRE AN			1		The property of the second of
(c) Who obtains the written physician orders	AND THE RESERVOIS THE PROPERTY OF THE PROPERTY		-	<u> </u>		The sales are seen and the company of the company o
they	will be made available of	The state of the s		-		The second secon
those involved with the client's care						
(e) Who maintains records for investigational drugs and controlled	id controlled			1	1	
substances						• 3
	drugs and supplies to the			1		The first intermediate control of th
clients in their home when not available from the p	the pharmacy					
(g) Mechanisms for evaluating the contracted service	T COMPANY OF THE PROPERTY OF T			-		AMERICAN STATES AND ASSESSED STATES OF THE STATES ASSESSED ASSESSE
DIII.2c Delivery of products and supplies when provided to clients under arrangement are in	nder arrangement are in		-	;		One Prototype
compliance with CIII.2 a-b, DIII.2a and, in addition, include	ude the provisions for:			<u>×</u>		
1) Ensuring clean and safe transport of equipment and sup	supplies	-		<u> </u>	-	The state of the s
2) Timely delivery of products and supplies	The second secon	:	-	1		eren branch (many) militarian manager is the bright company of the branch of the branc
3) Setting up equipment in client's homes, where appropriate	ate	-			1	e Name de mantino i autono de mande de mande de mande de la composition della composition della composition della composition della composition della composition della composition della composition della composition della composition della composition della composition della composition della composition della composition della composition della compos
4) Adequately trained delivery personnel	The state of the s		-			The second of th
5) Client education, where appropriate	Addressing in the second of the second of the second of the second of the second of the second of the second of	The second of th	-		-	
6) Appropriate documentation	And the state of t			-		THE NUMBER OF PROPERTY OF THE
/Program has adequ stated mission	ate and appropriate	The state of the s		<u> </u>	1	Compared to the Court of the Co
DIII.3a The organization has a contingency plan and/or policies and procedures to adequately	procedures to adequately			-	1	THE RESIDENCE CONTROL OF THE CONTROL
address cash or operating short falls that may impact the prod	products and services it	-		<u>×</u>		
provides.						
lue to gener	al liability, product liability,					
professional liability and work related injuries.	The state of the s		-			
DIII.3c New program, product or service planning and development occurs prior to	occurs prior to					
implementation which includes analysis of effectiveness and profitability of the	profitability of the					
project.						
DIII.3d The management team's performance reflects an understanding of the interrelationship	ng of the interrelationship		-			The second secon
of finances, quality, product and service operations and long term viability of the	term viability of the					•
organization.						

PHARMACY STANDARDS	IN PLACE	COMMENTS
	YES NO N/A A/R A/O	No. The many of additional control and the con
DITEM THE Pharmacy organization has adequate and appropriate physical facilities to accomplish its stated mission.		
DIII.4a The Pharmacy organization has the necessary space, equipment and supplies for safe		
preparation, dispensing, storage and delivery of pharmaceuticals in compliance with		
and federal requirements, and includes at a minimu	design of the second se	
- 1		1.00 (1994) Charles (1996) Charles (
2) Hot and cold running water with sink		
3) Walls, ceilings and floors made of non-porous cleanable surfaces		
- 1	The state of the s	The second control of the second of the seco
5) Adequate ventilation and lighting	The state of the s	
7) Adequate storage facilities	TRADITION OF THE PROPERTY OF T	THE COLUMN TWO IS NOT THE PROPERTY OF THE PROP
(a) Parenteral compounding items stored to maintain integrity of aseptic		
environment		
(b) Adequate refrigerator/freezer capacity to meet storage requirements for	And the state of t	
all refrigeration-required materials.		
(c) Shelves and storage containers made of washable, non-porous materials,	The state of the s	And the state of t
including non-use of corrugated cardboard/styrofoam		
DIII.4b The Pharmacy organization maintains adequate and clean compounding areas in	indigents between the control of the	TO THE PROPERTY OF THE PROPERT
compliance with its policies which specify:	×	
The adequacy of workspace per state regulations		
2) Frequency, types of cleaning agents and procedures of how work surfaces,		THE PROPERTY OF THE PROPERTY O
- 1		
3) Work surfaces are kept free of equipment, supplies, records and other material		
unrelated to the preparation of a given drug		
4) Certification of laminar flow hood per organizational policy and/or	TOTAL TRANSPORTED TO THE PROPERTY OF THE PROPE	The state of the s
5) Validation of cleaning and compounding practice including surface sampling,		AND THE PROPERTY OF THE PROPER
environmental air sampling and end product sterility testing for pyrogens.		
DIII.4c Storage of the final pharmaceutical product is in accordance with acceptable	The second secon	AND THE RESERVE AND THE PROPERTY OF THE PROPER
professional/community standards of practice which are supported by reference data,		
including temperature, light and length of time.	,	
DIII.4d Areas for compounding of sterile products are functionally separate from areas for the	The state of the s	And the second section of the content of the second of the content of the second of th
preparation of non-sterile products and are constructed to minimize opportunities for		
contamination of products.		

PHARMACY STANDARDS	IN	IN PLACE	- -	-		COMMENTS
	YES NO N/A	N 07		A/R A	M0	CATALLEL I I I I I I I I I I I I I I I I I I
DIII.4e There are adequate work areas for the preparation and manipulation of injectable drugs, which includes the following:						The second secon
Methods for inspecting ingredients and final products for the presence of inappropriate particulate matter or signs of deterioration or microbial contamination						
2) Use of laminar flow hoods				-	Company of the contract of the	THE REPORT OF THE PROPERTY OF
3) Use of Class II Biological Safety Cabinets for the preparation of cytotoxic drups			-	-		
DIII.4f Laminar Flow Hoods and Class II Biological safety cabinets are inspected at least		-	1	1	THE REAL PROPERTY AND ADMINISTRATION OF THE PROPERTY ADMINISTRATION OF THE PROPERTY AND ADMINISTRATION OF THE PROPERTY AND ADMINISTRATION OF THE PROPERTY AND ADMINISTRATION OF THE PROPERTY AND ADMINISTRATION OF THE PROPERTY AND ADMINISTRATION OF THE PROPERTY AND ADMINISTRATION OF THE PROPERTY AND ADMINISTRATION OF THE PROPERTY AND ADMINISTRATION OF THE PROPERTY AND ADMINISTRATION OF THE PROPERTY AND ADMINISTRATION OF THE PROPERTY ADMINISTRATION OF THE PROPERTY ADMINISTRATION OF THE PROPERTY ADMINISTRATION OF THE PROPERTY ADMINISTRATION OF THE PROPERTY ADMINISTRATION OF THE PROPERTY ADMINISTRATION OF THE PROPERTY ADMINISTRATION OF THE PROPERTY ADMINISTRATION OF THE PROPERTY ADMINISTRATION OF THE PROPERTY ADMINISTRATION OF THE PROPERTY ADMINISTRATION OF THE PROPERTY ADMINISTRATION OF THE PROPERTY ADMINISTRATION	
every six months and certified by an independent agency that they are operating						
according to specifications. Certification records are retained for a minimum of three vears.						
DIII.4g Pharmacy personnel using a laminar flow hood or a Class II Biological safety cabinet		1	1	1	And the state of t	AND THE PROPERTY OF THE PROPER
use proper techniques consistent with professional standards of practice to ensure a						
communes aschuc environment during the admixing of sterile pharmaceuticals.						
DIII.4h Preparation of injectables from sterile solutions includes the use of filters when		The state of the s		1	THE PARTY OF STATES OF THE PARTY OF THE PART	
removing solutions from ampules.						
DIII.4ilnjectables prepared from non-sterile powders are:				<u> </u>	A CAMPANIA MANAGEMENT OF THE PROPERTY OF THE P	
Dissolved in sterile solution for injection		-		1	THE MARK LANGER IS ANAMALISM AND THE CONTRACT OF THE OPERATOR STREET, AND THE CONTRACT OF THE	terren vermen de ser de la company de la company de la company de la company de la company de la company de la
2) Filtered through a 0.2 micron filter.					mentande de la companya de la companya de la companya de la companya de la companya de la companya de la compa	e de la companya
DIII.4] Respiratory medications prepared from non-sterile powders are prepared in an ISO 5						
듸		1				The second section is the second section of the second section in the second section is the second section of the second section is the second section in the second section in the second section is the second section in the second section in the second section is the second section in the second section in the second section is the second section in the second section in the second section is the second section in the second section in the second section is the second section in the second section in the second section is the second section in the second section is the second section in the second section in the second section is the second section in the second section in the second section is the second section in the second section in the second section is the second section in the second section is the second section in the second section in the second section is the second section in the second section in the second section is the second section in the second section in the second section is the second section in the second section in the second section is the second section in the second section in the second section is the second section in the section is the second section in the section is the second section in the section is the section
1	***************************************				Bandonistis in the state of the	
- 1		-		1	And the state of t	
3) Fackaged under ISO 5 environment conditions	,	-		1	To represent the state of the s	
Textoureany end product tested DIII 4kt Adequate shipping containers and shipping processes are used in accordance with		-	-	-	enter de amoles is des automobiles appelles, els enters de la production de l'est de l'est de la production de	a aman alimining strain settler than the settler of the manufactor of disquest of many amounts of the their complete settler and the settler of the settler
regulations and manufacturers guidelines to assure drug stability and potency which					,	
- 1			! !		A CONTRACTOR OF THE PROPERTY O	Principal despite company of the state of th
	The state of the s					
4) Non-exposure to contaminants	i					The state of the s
5) Packaging of medications in a tamper evident manner					The state of the s	THE RESERVE THE PROPERTY OF TH
DIII.4 The organization's physical facilities provide a safe environment for staff and clients						and the second s
1) Space and privacy are adequate for the services being provided		-		-	The second second and the second seco	
2) Physical facilities and resources nermit effective and efficient function of the		-	-	1	40-0 () () () () () () () () () () () () ()	ender (supper 1 (septem) (sem (y = 1) mass — sprengen, y — september (semantic (september (september) september (se
personnel						
3) Provisions are made to accommodate clients and staff with disabilities		-	$\frac{1}{1}$	1	rises in one disconnected and the contract of	
		-	1		Annual contract of the second contract of the	en de la company de manuer des manues des des des de manues (19 art), des plans de la company de la

	PHARMACY STANDARDS	IN PLACE			COMMENTS
		YES NO N/A A/R A/O	A/R A	0	
	OINES Ameffective and efficient management information system is utilized to				
DIII.5a	DIII.5a When available, the organization uses external databases that provide information	Service of the servic		- Value - Valu	A CONTRACTOR OF THE CONTRACTOR
	relevant to the organization's products and services and creates a basis for comparative				
	analysis.				
DIII.5b	DIII.5b The organization participates in a benchmarking system.	Andreas Control of the Control of th	×	i	PROTECTIONS AND IN THE ANALYSIS AND AND AND AND AND AND AND AND AND AND
	1) Benchmark data are consistent with organizationally defined goals and			<u> </u>	
	objectives				
	2) Benchmark collected data, when available, are measured against data from				AND THE PROPERTY OF THE PROPER
	other organizations	Comment of the Commen			

PHARMACY STANDARDS	de la companya de la companya de la companya de la companya de la companya de la companya de la companya de la	IN PLACE		COMMENTS
		YES NO N/A	A/R A/O	THE REPORT OF THE PROPERTY OF
UP IV LONG TERM VIABILITY			The statement and the statemen	Commence of the commence of th
Dest : Operational planning reflects the Pharmacy's mission.				
DIV.1a The planning process focuses on performance expectations and is consistent with	is consistent with			
DIV 16 The written plan is developed and the initial plan and changes are approved by the	are approved by the		Page 1 to 1 man to the second training of the	If Different From Core
governing body.			×	
DIV 2 An annual systematic evaluation of major aspects of the Pharmacy	he Pharmacy			lf Different From Core
Crganization's program and operations provides the b	es the basis for future		×	
DIV.2a Mechanisms are established in writing for the collection, dissemination and use of	nination and use of	The state of the s		Therefore the second of the se
information for the purpose of management, quality improvement, planning and future	ent, planning and future			
evaluation purposes.				
DIV.2b Data appropriate to the complexity and scope of the Pharmacy organization is	organization is			
collected and monitored.				
DIV.2c Pricing of products and services is routinely evaluated.				THE PROPERTY OF THE PROPERTY O
DIV.2d Results of the Pharmacy organization's evaluation findings are integrated into the	e integrated into the			The second secon
corporate organization's report, if applicable.	 An address in the later of the address	The state of the s		
DINE The Pharmacy Organization management team fosters	fosters innovation within			
🎉 🙀 the organization and brings strong leadership to industry-related	stry-related			
activities.	1.0			
DIV.3a A common and futuristic vision of the organization is established and sustained	ed and sustained.			
1) A learning environment for all staff is promoted and supported	oorted			TO THE PARTY OF TH
2) Staff development is encouraged				man was an in the service of the ser
3) Governing body members have expertise specific to the en	to the enhancement of the			
organization's mission				
DIV.3b An atmosphere of mutual respect permeates the organization throughout	ıroughout.			
1) Interaction between staff, administration and governing body is evident and	oody is evident and			
is facilitated	AND AND AND A SECURITION AND A PART AND ADD AS A SECURITION OF A SECURITION ASSECTATION AS A SECURITION ASSECTATION AS A SECURITION AS A SECURITION AS A SECURITION ASSECTATION AS A SECURITION ASSECTATION AS A SECURITION AS			
DIV.3c The organization has positioned itself to participate in public forums that shape health	orums that shape health			
care policy and educate consumers.		100		
DIV.3d The organization actively networks with other providers and provider organizations.	rovider organizations.			



SITE VISIT WORKBOOK

Site Visit Dates:	to	
Name of Organization:		
Address:	Telephone:	
	Fax	
	E-mail:	
Contact Person:		
Title:		
Medicare #	Medicaid #	
Other #		
Visit Type		
SITE VISIT	OR CITATIONS:	
Commendations Former Required Actions Met Continued as RA Continued as Rec	New Recommendations Medicare Tags Deemed Visit (4)	
Site Visitor Name	<u>Signature</u>	<u>Initials</u>
	p	

CHAP: 2/2005

EVIDENCE GUIDELINES	CITATION STATEMENTS
D = Documentation S = Survey	
O = Observation I = Interview	
_ ~	
D: Current Mission statement includes	
a consumer focus and orientation	
to quality. (CI.1)	
D: Consumers are defined as	
individuals, groups and	
communities. (CI.1)	
D: Governing body minutes document	
actions taken on the mission:	
(CI.1b)	
(a) Review and approval at least	
every 36 months	
(b) Revisions and updates as	
applicable	
D: Legal documents specific to the	
organization, delineate applicable	
elements of CI.2b which may	
include :partnership agreement,	
articles of incorporation, bylaws, state charter, state licensure, tax	
license, trade name registration,	
business license, amendments,	
medicare certification and special	
waivers.	
D: Note: Governing Body may be	
governmental entity. (CI.2c)	
D&I: Name, address, credentials and	
professional/business affiliation of	
each member is identified. (CI.2d)	
Note: Owner/Operator of a	
business may constitute the	
governing body.	
Governmental Boards of	
Health may be advisory in	
nature and/or may be elected	
or appointed officials.	
D&I: New member orientation is	
validated in writing. Governing	to the second of
body members describe the	
orientation experience and	
articulate key issues affecting the	
organization. (CI.2e)	
I: Governing body members articulate responsibilities and describe the	
types of actions taken by the	
board. (CI.2f)	
Note: Selected elements may not	
apply to owner/operator	
businesses, i.e., selecting the	1
chief administrator.	
	,
	F
	· ·

CIAL	Rublished Mission statement													
	clearly denuties commitment to	•												
	proxiding high quality services													
	&products which address									•				
Daniel Branch	consumer needs as a priority			<u> </u>										
Cl.1a	Programs & services reflect													
	organization's written mission		<u></u>									 • • •		
Cl.1b	Mission statement is reviewed/				-						•			
	revised as indicated//approved by													
SOURCE CONTRACTOR STREET	GB at least every 36 months													•
	Organization has structure &		-											
C12	nunciional mechanisms to sup-		2						'					
	port accomplish stated mission													
CI.2a	Legal authority to operate & is in		-											
G117, 118 L172, 173	compliance with local, state,													
	federal regulations													
C1.2b	Applicable Governance Structure													
G117, 118	is defined in legal documents													
	specific to the organization							<u> </u>						
Cl.2c	An identified governing body:							-						
G128, 129, G130	1) Assumes full legal authority/				·									
L107, 108	responsibility/accountability for													
L110	organizational performance													1
	2) Appoints a qualified													
L109	administrator													
	3) Designates advisory group													
	membership as applicable							ļ						
CI.2d	The GB is made up of individuals													
	with relevant expertise, business						-							
	acumen,, and professional													
i '	relationships specific to the stated													
	mission of the organization.													
CI.2e	GB members are oriented to the													
.	organization & are knowledgeable													
	& responsive to key issues													
	affecting the organization													
CI.2f	GB carries out responsibilities													
L107,8,10	specific to the organization including					ļ		 	<u> </u>					
G130,153 L108	1) Establishing policies consistent			ļ									,	
L100	with organizational mission				<u> </u>	-	ļ	-						
L108	2) Approving new/revised P&P's													
D100	as indicated & necessary				 	-		-						
G132	3) Holding management		^											
G134	accountable for the fiscal					and the second								
	solvency of the organization &													
	adequacy of financial resources					ļ	-	-						
G132, 147, G148	4) Approving budgets & capital			1										
	expenditures				1	 	1 .	-	-	1				
G129 L108	5) Selecting & evaluating the				1	· .								
LITTO .	chief administrator				 	 	-	-	-	1				
G246	6) Evaluating organizational					1								
U240	performance			<u> </u>		 		-	 	-				
	7) Developing & approving				1									
'	strategic plan					-	-	_	ļ	4				
	8) Periodically reviewing legal &					1.5								
1	business documents, at least													
1	every 36 mos.(Articles of	·												
	Incorporation, By-laws,													
-	Legal Agreements)			<u> </u>			<u> </u>					 		
	E Standards 2004 Site Visit Worldhook 2/2004													

EVIDENCE GUIDELINES	CITATION STATEMENTS
D = Documentation S = Survey	
O = Observation $I = Interview$	
D: Current signed and dated annual	
disclosure statements are on file	The state of the s
for all governing body members	
and executive staff. (CI.2g)	
D&I: Governing body members	
confirm adherence by governing	
body members to legal documents	
which may describe notice of	
scheduled and special meetings,	
attendance requirements at	
meetings, appointment of officers,	
terms of office, committee	
structure and function, quorum	
determination. (CI.2h)	
D: Governing body minutes reflect	
agenda items, discussion, and	
action taken. (CI.2i)	
Note: Closed sessions are to be	
documented and	
distributed/filed per	
organizational policy.	·
D: A current organizational chart is	
dated and reflects lines of	
authority and accountability for all	
personnel. (CI.3a)	
D: Amendments to the organizational	
chart are documented as	
applicable, (CI.3b)	,
I: Staff members are familiar with the	
organizational chart and state	
their individual lines of authority	
and accountability. (CI.3c)	
D: Current job descriptions are on file	
for administrative and	
management positions. (CI.4a, b)	
CEO/Administrator/Management	·
resumes validate experience,	
knowledge, and qualifications	
required for the job. (CI.4b)	
Note: This standard may pertain to	
the Chief Health Care	
Administrator in Public Health	
Organizations.	
D: Written policy and procedure	
defines assignment of	
administrative responsibilities in	
the absence of the	
CEO/Administrator. (CI.4c)	
I: Designated alternate to the	
CEO/Administrator understands	
his/her role and describes	
experiences specific to the	
alternate role. (CI.4c)	
atternate rote. (C1.40)	_

C1. 2g	Alliually, OD memoers &							*							
	executive staff provide written														
	disclosure of all professional &/or														
	personal relationships or interests,			ļ											
1	direct or indirect, that might						-						**		
06	represent a conflict of interest.			-	,				,		1.				
	Statements are on file in office.					1									
Cl.2h	The GB complies with														
0	organizational by-laws or other		, ,	[
	legal documents.														
C1.2i	Accurate, complete & signed														
C1.21												•			
	minutes are kept of all official														
	meetings of the GB, document														
	actions taken, distributed per							·						•	
	policy and retained 5 yrs mini-	-													
	mum or per state regulations.									•					
CL3	Intra-organizational relation- ships are clearly defined					·									
CI.3a	Current organizational chart							,							
	delineates lines of authority &							1							
G122, 123	accountability of all personnel														
CI.3b	Organizational chart is reviewed														
	and changed as needed														
CI.3c	Personnel understand & use the		***************************************							·					
	organizational structure outlined														
	in the organizational chart.												•		
CI.4	Aminority & responsibility for														
	oyeralladmuistration &														
	management is vested in														
	gualined und voluais														
CI.4a	Chief executive/administrator's														
C1.44	credentials include appropriate														
	industry experience and														
	knowledge of applicable local,												,		
	state and federal laws.														
CI.4b	Qualifications for administrative														
	& management positions are														
	defined in writing & are														
	consistent with scope of														
	responsibility & complexity of the														
	organization. Administrative/														
	mgmt personnel have equivalent														
	combinations of education/														
1	training/ experience to qualify for														
	assigned responsibilities							<u> </u>							
CI.4c	Qualified individual is designated														
	in writing to be administratively			·.											
G137	responsible in the absence of chief														
	executive/administrator					1									
CI.4d	Admin. & mgmt. responsibilities														
	are clearly defined & delegated as				1										
L124	specified and include:] .					
	1) Organizing & directing the		, .												
G133	organization's ongoing				1		1								
	operations to assure				1		1	r	1			*			
	availability and provision of			1											
	care & services	1		1											
-		-		<u> </u>	-	 	+	-	+	1					
	2) Implementing governing body						1								
	directives and organizational														
	policies & procedures.	<u> </u>	<u> </u>	7		<u></u>			1	<u></u>					

EVIDENCE GUI		CITATION STATEMENTS
	= Survey = Interview	
I: CEO/Administrative	1	
Management person their respective are	as of	
responsibility. (CI.		
I: Management and advisory/governing	hody members	
describe process for	r development,	
revision and annual policies. (CI.5a)		
D: Administrative polici procedures address	the areas	
delineated in CI.5b. D: A written safety pro	1	
parameters for mon	nitoring	
identifying potentia in accordance with	l hazards/risks	
as biomedical waste storage and handlin	e management,	
environmental clear	ning supplies,	
fire safety, preventi of equipment, repor	rting of	
malfunctioning equ environmental cont	rols to prevent	
client or staff accide incidents and safety	of clients and	
employees in the co (CI.5b)	mmunity.	
	-	

G1 18	laws & regulations								-
	4) Recruiting, employing &								*
	retaining qualified personnel to								
34	maintain appropriate staffing								
1	levels	<u> </u>							
G. D.	5) Ensuring adequate staff								•
G134	education						,		
	6) Completing performance								
G134	evaluations on subordinate			-					
0.27	staff in accordance with								
	organizational policy				 				
	7) Directing/monitoring						·		•
	organizational Performance								
	Improvement activities				 				
G136	Managing operations in accordance with established								
	fiscal parameters								
	9) Planning, developing,								
	implementing, administering &								
	evaluating programs								
	10) Representing the organization								
	to other groups, organizations								•
	& the general public								
	11) Ensuring the accuracy of				 				
G135	public information materials								
	12) Informing the GB & staff of								
G133	current organizational,								-
	community & industry trends								
CI-5	Organizational P&P/stieflect an								
	emphasision quality & ethical							i	
	practice & nelate directly to the						,		
	mission of the organization								
CI.5a	P&P's are developed, revised &								
G153	reviewed annually to ensure currency of information .	-							
CI.5b	Administrative P&P's delineate							Ĺ	
01.50	administrative authority &								
	responsibility for governance,		ļ						•
	planning, financial control &								
	personnel,								
	Policies include at a minimum:								
	1) Written disclosure of conflict of								
L106	interest								
G119, 120	2) Public disclosure of								
L106	information								
	3) Responsibilities of ethical								
	issues review group						<u> </u>		
	4) Rights & responsibilities of		. The state of the						
	clients						1 /		
	5) Internal & external complaint								
	management								
	6) Exposure control plan				 				
	7) Formal safety program								
	8) Financial policies & procedures								
	9) Research activities/investiga-								
	tional studies as applicable		1				1		
COREG							<u></u>		

EVIDENCE GUIDELINES	CITATION STATEMENTS
D = Documentation S = Survey O = Observation I = Interview	
D: Operational policies and procedures detail planning,	
delivery and evaluation of care and	
include the 16 elements of CI.5c.	•
D: Personnel policies address the 9 elements of CI.5d.	
	·
•	,
	·
	·

	framework for planning, delivery									•
	& evaluation of care & services								1.	
	provided.									
	Policies include at a minimum:				<u> </u>	-				
1	1) Non-discrimination statement				·					
	addressing admission of clients									
	to service		<u> </u>		. ^ .	-				
	2) Defined criteria for acceptance/									
G156	non-acceptance of clients					 				
	3) Admission, continuation of		ĺ				}			
G153,157	service & discharge		<u>.</u>					ļ		
	4) Standardized assessment		ļ							• ,
G330	process					ļ	↓	ļ		
	5) Referral to other providers of			1						
	care/services							ļ		
G158, 163,	6) Medical orders, verbal orders &									
G166, 300	physician oversight as								ļ	
•	applicable									
	7) Emergency service									
	8) After hours service									
G111,239,	9) Confidentiality of protected									
G240, 241	health information							·		
	10) Emergency /disaster									
	preparedness								<u> </u>	
	11) Health, safety & security of									:
	staff during all hours of work									
	12) Services/products provided									
	directly & under contract			*						
	13) Standards of practice for all									
	disciplines as applicable									1 · · · ·
1	14) Standards of operations for all		<u> </u>							
	products as applicable									
G121	15) Infection control			1						
	16) Accepted medical term									
	abbreviations			İ						
CI.5d	Personnel policies are developed		-							
	& revised in response to									
G141	organizational change & include:									
	1) Conditions of employment								1.	
	2) Respective obligations between									
	employer & employee						1 .			
	3) Non-discrimination information				1					
	4) Grievance procedure			1.	1	T				
	5) Employee orientation	<u> </u>								
	6) Employer exit interviews	-	 							
	7) Maintenance of health reports	-		+	+					1
	& protected employee information			į						
	8) Employee record confiden-	 	-		-	 		_		-
	tiality & record retention									
	9) Recruitment, retention & per-	 	-	-	-	_	_	_		_
	formance evaluation of staff						.			
CIT #		 	+	-	+		+	_	-	-
CI.5e G121										
G1.201	Plan is in compliance with the								1	<i>e</i>
	most current CDC applicable									
	recommendations & requirements									
:	for occupational exposure to TB.	<u></u>				l				

EVIDENCE GUIDELINES	CITATION STATEMENTS
D = Documentation S = Survey	
O = Observation I = Interview	
D: Written TB Exposure Control Plan includes the elements in CI.5e.	The second secon
D: Written policy and procedure define the requirements of Medical	
Device Act reporting. (CI.5f)	
D: Medical Device Act reports, as applicable, are on file in the	
organization and include validation of submission to the	
FDA which may include an incident that results in death and	
when the manufacturer is unknown. (CI.5f)	
and the second second	
,	
	•

C1.5e	The plan addresses:												•	
(cont'd)	1) Definition of employees at risk			1	1		1		41.1	1	5. ·			
	of occupational exposure to TB					1								
	2) Process for identifying									1				
)	suspected or confirmed cases	-												
L	of TB									1	v			
	3) Control of employee exposure							<u> </u>						
	when a client is suspected or				1, 4,				131.4			a see yaar ah ah ah ah		
	confirmed as having]					i					
	infectious TB				ĺ									
	4) Education of all employees to				T .	-								
	the hazards of exposure to TB			ļ										
	at time of hire & annually							٠.						
	thereafter													
	5) Pre-employment & subsequent													
	periodic TB screening of													
ma rin	employees in accordance with													
	written policy													
	6) Provision of follow up care to													
·····	employees exposed to TB													
	7) Provision of follow up care to													
	employees who convert to													
	active disease													
	8) Provision of appropriate													
	personal protective equipment													
	when caring for a suspected													
	confirmed TB client													
	9) Provision of work practice												•	
	oversight to minimize	}												
	occupational exposure to TB													
	10) Adherence to reporting &	1												
	record keeping requirements													
CI.5f	per state/federal law													
CISI	Organizational P&P'S address the													
	requirements of the Medical Device Act (MDA) & delineate							1						
	the mechanisms for reporting	Ì	ļ											
	incidents which result in serious								İ					
	injury, illness or death			Ì										
***************************************	1) Reports are filed with the													
	Federal Drug Administration	İ]							
i	according to regulation	1	ļ				;							
	2) A designated person is													
	responsible for ensuring	1				.								
	compliance with reporting			ĺ										
	requirements	1		ŀ		.								
***************************************	3) Criteria for designation of													
	reportable events are defined			-			***************************************							
	4) Written protocols for													
	investigation of events are					-								
	defined													
-	5) Investigative activities are													
	initiated on a timely basis													
											·			
			<u>l</u>											

	EVIDENCE GUIDELINES	CITATION STATEMENTS
	D = Documentation S = Survey O = Observation I = Interview	
D :	Medical Device Act reports, as	
	applicable, are on file in the organization and include	
	validation of submission to the FDA which may include an	
	incident that results in death and when the manufacturer is unknown. (CI.5f)	
T	XXI like the first of the second and believe	
D:	Written infection control policies and procedures include the elements in CI.5g.	
	elements in C1.5g.	
		·
• .		
	•	

	b) Accurate documentation of					i i				,	
	findings include:	<u> </u>			<u> </u>						
	a) Investigative findings										
	b) Copies of reports sent to					1.					
<u> </u>	manufacturer	1									
1	c) Copies of reports to the FDA								-		
	7) Retention & retrieval of										
	findings & reports				1		-				
	8) In-service education on MDA										
	reporting is provided to staff on					1			+		
	an annual basis										
	a) Written curriculum outlines		<u> </u>								
	training content										
	b) Records of attendance are										
	maintained										
CI.5g	Infection Control P&P's detail										
	systems designed to promote the										
G121	prevention & control of infections,									•	
	monitor the occurrence of										
	infections & evaluate the			1							
	effectiveness of infection control										
	practices				1						
	1) Current infection control										
	practices & strategies										
	2) Identification & investigation										
	of breaks in technique	ļ									
	3) Sources of infection:										
	a) Nosocomial										•
	b) Home acquired										
	c) Professional exposure					<u> </u>					
	4) Types of infection	·								•	
	5) Modes of transmission of										
	infection										
	6) Contributing causes of										
	infection										
	7) Data collection, analysis,										
	tracking & trending of findings				<u> </u>	ļ	ļ				
	8) Reporting requirements per							1			
	state & federal regulations	 		ļ		ļ	ļ				
	9) Documented evidence of in-										
	service education for staff								-		
	includes:								***		
	a) Dates & times of programs		1		1						
	b) Curriculum outline of										
	training content										
	c) Records of staff attendance		-		+			 	-{		
	10) Client/family teaching	 	-	ļ	-	-					
	11) Use of personal protective		1								
	equipment/supplies		 	-	1	-			-		
	12) Accepted hand hygiene					1					
	techniques		1								
			1				<u> </u>		<u> </u>		

EVIDENCE GUIDELIN	NES	CITATION STATEMENTS
D = Documentation S = Survey		
O = Observation $I = Interview$	w	
	4	
D. Weitten policy and precedu	110	
D: Written policy and procedu define the parameters for e	menring	
the safety, security, and	Jugui IIIg	
confidentiality of clinical		
hardcopy, automated, and/	or ·	
travel records. (Ci.5h).		
D: Written policies and proced	lures	
define the parameters that	ensure	
the client's right to access o	client	
record information and rel	lease	
client record information.		
D: Written policy and procedu		
local/state/federal regulation		
dictate the secure retention	1	
types of clinical records. (C		
D: Written policy and procedu		
details the process for releatinformation. (CI.5h)	11 35 UI	
I: Records administrator or of	ther	
designated party describes		
adherence to policy and pr		
(CI.5h)		
I: Staff describe process for ac	ccessing —	
policies and procedures. (CI.5i)	
D: Informational materials, wi	ritten in	
different languages are ava		
and provided to clients/fan	nilies as	
appropriate. (CI.6a)		
I: Administrative/management		
personnel articulate cultur diversity in the community		•
population and describe th		
organization's ability to m		
special needs. (CI.6a)		
I: Staff members demonstrate		
awareness and use of avail		
resource materials, and		
lients/families verbalize kn		
of pertinent resources. (C.		
I: Clients/families of different		
acknowledge receipt of lan		
specific materials and care		
provided by bi-lingual statemembers and/or the use of		
members and/or the use of interpreters as appropriat	ſ	
necessary. (CI.6b)	anu anu	
necessary. (CL.UD)		
[

CI.5h	Administrative, financial, client &													
	personnel records are retained &													
-	retrievable in accordance with													
	formal record retention policy that													
I g	is in compliance with					-		.]			-			
76	organizational policy &		,											
	local/state/federal law													
	1) Minutes of all official meetings			l							•	14		
	of GB are retained for a													
	minimum of 5 years													
	2) Client adult records are retained													
G237	for a minimum of 5 yrs after													
	the provision of service													
	3) Client records of minors are													
	retained for a minimum of 7										•			
	yrs after age of majority is reached													
C112 240				,										
G112, 240, G241, 310	4) Mechanisms for client access &													
L183	release of client records are												•	
	defined													
L178	5) Authorization for client record	-												
L179	documentation & entry &													
	signature authorization/				·									
	authentication for automated													
	client record system in													
	accordance with individual													
	state law are defined.													
G111,239	6) Process for maintaining safety													
L186	& security of client records													
	is defined.													
	7) Confidential records for													
G121	employees experiencing an													
	occupational exposure are													
	retained for the duration of													
	employment plus 30 yrs									·				
G121	8) Annual training records for													
0.21	exposure prone employees are													
	retained for a minimum of						3							
	3 yrs													
	9) Client records involved in													
	litigation are retained until after settlement			1				'						
OT FI	Staff members have access to			<u> </u>										
CI.5i														
	policies & procedures.									1				.7
CL6	Antonnutionals provided to													
G118	clients/families identifying the													
	savailability of organizational &							1						
	meening ulien inceds			-		<u> </u>	 	 		1				
CI.6a		}												
G118	materials, as necessary & appropriate, are available for			1.										
	distribution to clients/families													
CTAL				 		-	+	 		1				
C1.6b	Interpretive services are provided,							***.						
	as indicated & necessary, to	r.					1							
	ensure accurate communication				1									
	between client/family/caregiver &		i											
L 28	other types of health services	-		1 .										
	personnel													
			<u></u>	7.	<u> </u>	<u> </u>	<u></u>	<u></u>	<u></u>	<u></u>				
	tandards 2004 Site Visit Workbook 2/2005			_										

EVIDENCE GUIDELINES	CITATION STATEMENTS
D = Documentation S = Survey O = Observation I = Interview	
D: Written policy delineates the make	
up and function of the designated group to review ethical issues.	
Authority may be self-vested in the governing body, in an independent	
entity or in an advisory group. (CI.7a,b)	
I: Administrative/management/staff personnel describe the structure of	
the ethical group and the process for handling ethical concerns and	
issues. (CI.7b) D: Meeting minutes document	
discussions of and actions taken by the group, ass applicable. (CI.7c)	
I: Administrative/management	
personnel describe that careful consideration is given to providing	
a site for relevant research, human subjects involved in any part of	
research activities provide written informed consent, and that specific	
parameters for protection of participants and confidentiality of	
personal information are clearly defined. (Cl.8a)	·
D: Policy and procedure establish the parameters for research initiatives	·
as applicable. (CI.8b) D: Current research activities as	
applicable ensure compliance with CI.8a,b,c,d.	
I: Administrative/management personnel describe current	
research initiatives as applicable. (CI.8c)	
I: Staff describes use of research knowledge which was integrated	
into practice as applicable. (CI.8e)	

	clinical, disease prevention & health promotion activities are conducted according to ethical standards	<u>-</u>											a.	
CI.7a	. A group of qualified professionals					•								
	is designated by the GB to review													
	ethical issues as they arise													-
Cl.7b	Organizational P&P outlines						. •				. •			
	responsibilities of the group &				İ									
	delineates the process for							٠ ا	,			•		
*.	submitting ethical concerns &													
	issues for action													
CI.7c	Meeting minutes clearly document													
	group activities & are referred to													
	the GB for review & final action				-									
	as indicated & necessary													
C1.8	The organization considers requests for research in the area of community/public health as appropriate													
CI.8a	A mechanism is in place for													Ì
	reviewing, processing &							Ì						
1	approving internal & external													-
	research proposals													
CI.8b	Organizational P&P'S define													
	parameters for participation in											*		
	research activities & investigative													
	studies	* 4												
	1) Research protocols, as													- [
	applicable, for internally &													
1	externally sponsored activities													
	are on file													
	2) Potential participants are													-
	provided written information													
	regarding the nature, process &													
	benefits of the research													
	outcomes				-		 			-				
	3) Risks associated with the													
	project are clearly delineated			ļ	-			-	-	-				
CI.8c	Organizations participating in									-				
	research or investigative studies											•		
*	ensure that clients & staff are fully									1				
	informed					ļ	-							
CI.8d	Formal written consents for													1
	participants in research &/or					ľ								
	investigative studies are obtained									}				
	& retained on file in the					1								
	organization.		-			 	+	+		+				
CI.8e								-						
	external research is integrated into		***************************************											
	practice, as applicable.													
		<u> </u>	1								 			

	EVIDENCE GUIDELINES	CITATION STATEMENTS
	D = Documentation S = Survey O = Observation I = Interview	
D:	Current Public Disclosure Policy addresses applicable elements of	
	CII.1a.	
D:	The Client Bill of Rights includes the elements of CII.1b.	
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CII.I	The mission drives the activities														
	of the organization & ensures				1			1.							
	public disclosure, client rights &							ľ							
had the	ethical standards of business &						1								
.01													•		
The same of the sa	Chircal practice			 	 		 	-							
CII.1a	Public disclosure policy defines	-													
	availability & accessibility of						Ī			-					
G117	public information & includes:														
GII.	1. Ownership information										•				
L106	2. Statement of organization's						ļ								
	Mission			-				1							
	3. Licensure & accreditation status							,							
GUII	as applicable				-	 		 							
CII.1b	A written Client Bill of Rights														
•	recognizes, protects & promotes														
	the right of each client to be					1	}		l						
•	treated with dignity and respect										•				
-	1) Written P&P'S defines rights &						ŀ								
	responsibilities of clients														
	2) Notice of rights is provided to			<u> </u>	1	 									
G102				1		1			1						
0102	clients in advance of providing				1										
	pre-planned care					ļ	ļ	 							
G10.4	3) Client is knowledgeable of														
G104	right to exercise rights at any time .						<u> </u>	ļ							
	4) Organization maintains docu-			ĺ	1								•		
G103	mentation of compliance of														
	distribution of required	-					1								
	information to clients.													•	
	5) The client/client's designated				 					1					
ገ4	representative is authorized to						ļ								
	exercise their rights			ļ		 	 	 	ļ	-					
G111	6) Confidentiality of client						1				•				
GIII	record/data is maintained by														
	the organization														
	7) Access to care/services is based			Ì											
	upon non-discrimination			İ											
	8) Clients are informed of right to												•		
	voice complaints/grievances to the														
G106	organization regarding treatment/														
	care/service without fear of				l .										
							1								
	discrimination or reprisal for					Ì							•		
	doing so			 	-		-	+		-					
-	9) Organization provides client								-						
	telephone # of the CHAP hot line,														
	including hours of operation &							1							
	purpose of the hot line to receive														
	complaints or questions about the				1										
	organization.			.]											
	10) Clients are informed of right				-	 	—	1	1	1					
G109					1										
	to participate in the development	1													
	of care/ & service plans.			-		 			+	-		•			
0140	11) Clients are informed verbally				1									•	
G113, 114,	and in writing prior to start of care						ľ								
G115	and as changes occur of billing/									1					
-	reimbursement methodologies,						1								
	including fees for			1											
				1											
	services/products provided,				4	4 4									
	direct pay responsibilities, &														
	notification of insurance coverage				-	1 - 3									

TE VISITOR DATA COLLECTION WORLDOOK

D = Decementation S = Survey O = Observation I = Interview I: Clients confirm the timely receipt of the Client Bill of Rights and other admission information. (CII.1c) Note: Advising clients of their rights is not applicable under conditions of emergency/disoaster intervention and mass clinics. D: Documented evidence in the client records confirms receipt of the Client Bill of Rights and other admission information. (CII.1d) Note: Advising clients of their rights is not applicable under conditions of emergency/ disoaster intervention and mass clinics I: Clients/families articulate understanding of the information provided and describe how they have found the information to be helpful (CII.1d) I: Clients/families describe methods used to contact the organization during regular hours of service, after hours, weekends and holidays. (CII.2a) I: Professional, technical, and support staff describe coordination and collaboration between disciplines. (CII.2b) I: Professional, inchnical, and support staff describe coordination and collaboration with sub-contract and/or independent contractor providers of care. (CII.2b) I: Clinical supervisors and staff describe the on-call system for services after normal organization hours. (CII.2c) O: Testing the after hours on call system validates compliance with organization polic & procedure. (CII.2c) D: Written information distributed to	EVIDENCE GUIDELINES	CITATION STATEMENTS
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organization policy & procedure. (CII.2c) D: Written information distributed to	O: Testing the after hours on call	
(CII.2c) D: Written information distributed to		,
D: Written information distributed to	organization policy & procedure.	
	(CII.2c)	
clients/families address	clients/families address	
disasters/emergencies as applicable	disasters/emergencies as applicable	
to the organizations service area.	to the organizations service area.	
(CII.3a)		
I: Clients/families are aware of their		
responsibilities in the event of an		
emergency episode. (CII.3a)	emergency episode. (CII.3a)	

		NIVI		iviet	Com	14141	KA	Rec	1171	
CII.Ic	Written admission documents				1	· .				
	provided to client or the client's									
	representative prior to the start of									
ì	care or at the time of initiation of									•
1	care/service ensure organizational									
G101, 102	compliance with Client Bill of									
	Rights and other regulatory		,							•
	requirements									
CII.1d		<u> </u>								
CILIU	A reasonable attempt is made &									
	documented to ensure that client									
G101, 102,	& family understand their rights &									
G103, 104	responsibilities which are									
0102,	reviewed with client prior to start	·								,
	of care or at time of initiation of									,
	care and periodically reviewed									
	thereafter					<u> </u>				
CIJ:2	Care, services & products are									
	available to & accessible by the									
	client/client/s representative									
CII.2a	Care, services & products are									
	provided within an established					·				-
	time frame, as specified by									
	organizational policy,									
	organizational standards, medical									
	directives or individual physician									
	orders. Consideration is given to									
	the client &/or family in									
	scheduling & providing care									
CII.2b	Collaboration & networking with							 		•
C11.25										
	other providers enhance provision									
L	of care & services as applicable									
C11.2c	Supervisory & clinical/service									
	staff demonstrate knowledge of									
	organizational P& P for ensuring									
	delivery of care, services &	-								
	products to clients									
CIL8	A geographic specific plan.							 		
	defines protocols for prioritizing									
	the delivery of care & services									
	to chents & protects the safety of									
1304	staff during disasters.									·
	eneigencies and/or									
	environmentally challenging						1			
	situations									
CII.3a	Detailed written instructions are						 	 	<u> </u>	
	given to the client/family to									
	•									
	ensure an appropriate & timely				}					
.	response on the part of the				}	1				
]	client/family in the event of a				1	1.				
	natural disaster, inclement									
	weather & or other emergent									
	event that might cause an									
	interruption in the provision of							'		
	services.				1	1				
							1			
								1		
						11	<u>L</u>			

EVENDUCE CUIDELINES	CITATION STATEMENTS
EVIDENCE GUIDELINES	CHAIION STATEMENTS
D = Documentation S = Survey O = Observation I = Interview	
O - Observation 1 - Interview	
D: Staff are oriented to written	
protocols that ensure the safety	
and security of personnel. (CII.3b)	
D: Disaster drills are documented as	
applicable to the organization.	
(CII.3c)	
I: Administrative/management staff	
describe roles and responsibilities	
of personnel during an emergency	
episode. (CII.3c)	
I: Staff members at all levels	
demonstrate awareness of	
responsibilities to ensure the safety	
of self and others. (CII.3c)	
D: Client records document	
coordination of care activities,	
including planning,	
implementation, monitoring and	
evaluation of care/service as	
appropriate. (CII.4)	
I: Clinical/service, financial, and	
operational staff describes	
collaboration and support among	
all disciplines and organizational	
divisions. (CII.4a)	
O: Organizational planning meetings	
as available and appropriate.	
(CII.4a)	
I: Professional, technical, and support staff describe protocols that	
protect client/family information	
regarding confidentiality of	
information, use of travel record	
and transport and storage of travel	
record. (CII.5a).	
I: Office staff describe ongoing	
security of client record	
information. (CII.5a)	1
I: Staff is knowledgeable of the client's	
right for access to and release of	,
client information. (CII.5a)	
O: Active and inactive client records	
are maintained in a secure area	
during working and non-working	
hours that is inaccessible to	
unauthorized individuals. (CII.5a)	
S: Random sample of client records	
reviewed provides evidence of	
compliance with organizational	
policy, standards and regulatory	
requirements. (CII.5c,d)	
O: Automated client record systems	
include safeguards. (CII.5e)	

CII.3b	Written protocols define			,	•						-	4.7		1
	management responsibilities in							1						
	ensuring the safety& security of							.						
	staff prior to or during an								.					
. \	emergent event		<u> </u>	<u> </u>										
CII.3c	Staff are knowledgeable of the													
L304	practices & procedures relative to							-						
-	emergency preparedness											٥		
CIL4	responsibilities & emergent events Inter & intra organizational			ļ										
	coordination is evident in the			-								•		
	planing implementation				-									
	monitoring & evaluation of care	7												
	& services provided													
CII.4a	Coordination between													
G143, 144	clinical/service, financial &								-					
0143, 144	operational components of the													
Water of the Control	organization is evident				<u> </u>									1
CIL5	Chent records, maintained for													
	each client or client group; are utilized as a fool for					-								
L176	coord mation of services (45.4)			-										
	Jegal document that is													
	descriptive of care & services						1							
	provided & as nacesource						1							
	document for billing &			İ							•			1
	nembusement.				ļ.									
CII.5a	All protected health information													
	or client records, hardcopy or automated, are kept confidential			}										
	and safeguarded against loss or													1
11,239,	unauthorized use in accordance								·					
G310	with organizational policy &						-							١
L186	local/state/federal regulations													
CII.5b	Clients have access to their													
G112, 240	records & are informed of the													
	process					ļ		-						
CII.5c	The client record documentation													
G235, 236	provides client information													
	specific to care & services/products provided,									ŀ			,	-
L176, 177 L182, 184	current client status & progress					1								
L185	toward goals & outcomes of care				1									
C11.5d	Entries to client record					1		Santa San						
C166 220	documentation is made only by						1.							
G166, 239	authorized staff & in accordance					1								
L178, 179	with organizational P&P					-	·	-	-	-				
CII.5e G239	Automated client record systems					·								
L186	ensure consistent & ongoing			}										
CII.5f	security & protection of data The format for maintenance of	-			_	-		-	+	1				
C11.51	client records is reviewed &	-			1		:							
L176	updated as necessary							ŀ						
CII.5g	Organizations with alternate sites	 	 	7	1	1				1				
	ensure consistent documentation,													
	communication, coordination &													
	retrieval of significant								}					
(1	administrative & client/family													
6.25, 126	information						1						 	

CITATION STATEMENTS EVIDENCE GUIDELINES D = Documentation S = Survey O = Observation I = Interview SI: Client records administrator describes process for ensuring consistent, ongoing validation and protection of automated records data including prevention of lost data due to equipment failure and storage of backed-up files. (CII.5e) I: Evidence is provided validating periodic review and updating of the record format used. (CII.5f) I&O: Managers/staff describe and demonstrate compliance with policy and procedure governing the coordination, transport, and security of information shared with and between alternate sites. Staff describe the type of information that is maintained and the procedures for coordination, communication, exchange, and retrieval of required information with the parent organization. (CII.5g) D: Data reflect measurement of quality of services outcomes. (CII.6a) I: Performance improvement manager describes rationale for the performance improvement process and the definition of specific client/service outcomes. (CII.6b,d,e) D: A structured framework exists. (CII.6c) D: A client satisfaction survey for the current year is available for review and includes at a minimum client satisfaction with care and services provided and satisfaction with providers of care. (CII.6f) I: The organization describes the mechanism for monitoring client satisfaction. (CII.6f) D: Evidence exists of utilization of performance improvement findings to resolve problems and improve quality of

service/products. (CII.6g)
D: Organizational committees and

governing body minutes document reporting of trends of performance improvement findings. (CII.6h)

CH16	A comprehensive Performance : Improvement process integrates			•								٠		1.1	
	the organization's Mission &				1.20				.						
	-promotes an organizational														
	wide approach that selects,														
	dieviews & analyzes outcomes specific to organizational needs				l										
	& scope of services/products						I								
Cil.6a	Quality is defined and measured														
	in terms of client/service			• •							•				
	outcomes												*		
Cll.6b	Specific outcomes are targeted for														
	improvement or replication														
CII.6c	The organization develops a														
L141, 142	structured framework for the														
	investigation of target outcomes														
Cil.6d	The organization identifies	•													
	outcomes to benchmark by utilizing internal standards/		-												
	processes/ protocols, practice/					1									
	service guidelines, industry														
	research &/or best practices														
CII.6e	The organization continually														
G249	evaluates progress toward														
G249	outcomes & identifies new areas														
L145	to improve or replicate as														
	indicated by results of data														
CII.6f	analysis A process for monitoring &														
Cirio	measuring the satisfaction levels														
	of clients is conducted at least														
	annually		-		-										
CII.6g	Performance Improvement														
G245	findings are:														
	1) Used to resolve identified														
L142 L143	problems														-
L143	2) Used to improve quality of services/products														
L145	3) Incorporated into program														
	planning/modification/														
	enhancement								ļ						
CII.6h	Trends of Performance					-			1:						
G245, 246	Improvement findings are														
L142	reported to appropriate														
L143 L145	organizational committees & the GB		,												
TEDITA VIEW	The health & safew of				-		 	 		1					
	employees & clients is phomoted.														
	& enhanced obtoquent addression.														
	entrational continues and a second														
	conmol practices &	i i													
	implementation obappropriate						1								- [
	sarety measures						1.								-
						1		1							

	EX	IDENCE GUII	THE INES	CITATION STATEMENTS
		Documentation		
		Observation	I = Interview	
	0 -	- Onsei vation	1 - Interview	
ъ.	Done	sonnel records inc	ludo avidanca	
ν:		idherence to regul	t t	
		uirements of Fede		
			erai OSITA	
ъ.		CDC. (CII.7a)	n a wa ma a tawa	
บ:		tten plans define j		
		exposure control,		
		versal precaution		
		vork practice con		
		phylaxis and TB	exposure	
_		trol. (CII.7b)		
D:		ential for employe		
		ermined by job cl		
		ch defines the pot	tential for risk	
		includes:		
	a)	Definition of typ		
		and/or procedur		
		an employee at r	risk for	
		exposure.	_	
	b)	Description of jo		
		classifications in		
		employees have		
		for occupational		
	c)	Description of jo		
		classifications in		
		employees have		
		for occasional ex		
	d)	Description of jo		
		classifications in		
		employees have		
		occupationally r		
		exposure. (CII.7		,
Ο:		ff demonstrate ad		
		ndard precaution		
		ermined by organ	nizational	
		icy:		
		Use of gloves		
	b)	Use of and acces		
		masks and prote		a week made a
	c)	Use of protective	e gowns and	
		aprons		
	d)	Hand hygiene/ha		
		techniques inclu		
		chemical substan		
	e)	Techniques for 1	minimizing	
		needle sticks		
	f)	Use of puncture		
		sharps container		
	g)	Proper transpor		
		storage of sharp		
	h)	Disposal of cont		
		supplies and equ	ipment on site	
		(CII 7d)		· ·

CII./n	Adherence to regulatory									
	requirements that address the									
,	health & safety of employees &									and the second of the second o
	clients & their protection from									
1	blood borne pathogens is									
G121	validated									
GIZI	1) State &/or Federal OSHA]							
L105	mandates as applicable									
	2) CDC recommendations &								,	• *
	guidelines									
CII.7b	The organization implements its									
L305, 308	written Exposure Control Plan									
C11.7e	The potential for occupational									
	exposure is determined for all job									·
	classifications in accordance with									
	state/federal & Occupational									
	Health & Safety Administration									·
	(OSHA) mandate									·
CII.7d	Adherence to the use of Standard									
	Precautions by job classification is									
	documented									
CII.7e	Adherence to work practice &									
	engineering controls is evident in		}							
	practice									·
	1) Physical work sites are									
	maintained in clean & sanitary							Ì		
	condition	İ								
	2) Use of disinfectant solutions									
	3) Handling, transporting, storage									
	& processing of									
1,307	soiled/contaminated materials,									
2307	supplies & equipment									
	4) Use of non-leak infectious									
	waste containers as applicable									
	5) Identification & labeling of									
L307	infectious waste as applicable									
CII.7f	Employer & employee									
	responsibilities relating to									
	Hepatitis B prophylaxis (HBV)									
	are defined in writing & include:									
	1) HBV vaccination & exposure					1				
	follow-up program									1.
	2) Employer/employee									
	responsibilities									
	3) Declination of HBV statement								1	
	is signed by employees as								'	
	applicable & filed in	1								
	personnel health records			1]
	4) Complete & detailed									
	documentation of all exposure	:								
	events						1			
	5) Confidential records are				1		1			
	maintained on HBV vaccination									w. · · ·
	& post exposure follow up				-					
									,	
1		1	1							

THE VISITOR DATA COLLECTION WORLDOOK

EVIDENCE GUIDELINES	CITATION STATEMENTS
D = Documentation S = Survey O = Observation I = Interview	
S: Random sample of employee	
records provides evidence of	
compliance with Hepatitis B	
(HBV) prophylaxis program.	
(CII.7f)	
I: Designated person describes	
procedure followed to ensure	
compliance with investigative	
requirements and protection of the	
rights of the employee who has	
experienced an occupational	
exposure. (CII.7f)	
D: Education and training records document compliance with	
training requirements. (CII.7g)	
D: Occupational exposure information	
is maintained in confidential	
records that are retained for the	
duration of employment plus thirty	
(30) years. (CII.7h)	
I&O: Clinical, technical and support	
staff describe potential hazards in	
the home setting identified during	
the assessment of the client's living	
environment. (CII.7k)	
D&I: Evidence exists that the	
organization monitors and reports	
information related to adverse	
events. (CII.71)	
Adverse events include but are not	
limited to:	
 Provision of care errors 	*
 Unusual occurrences 	
 Vehicular crashes 	
 Other types of accidents 	
or injury	
 Safety hazards 	
Serious Adverse Events include but	
are not limited to:	,
Unexpected death not	
resulting from the clients	
medical condition	
• Loss of body part	
Permanent or partial loss	
of body function	
• Blindness	
(CII.7l – Cont'd next page)	

C11.7g	Education & training programs								
	ensure that:								
	1) New employee orientation				-				
	addresses all aspects of the						"		
1	Exposure Control Plan						′		•
1	2) Annual training is mandated for								
	all exposure prone employees								
	based on applicable job						,		
	classification								·
C11.7h	The organization demonstrates							-	•
	compliance its Occupational		i.	ļ					
	Exposure Control policies, plan,			-					
	& procedures								
	1) HBV is provided at no cost to								
	all employees, potentially								
	subject to occupational								
	exposure, within 10 working								
	days of assignment								
and the state of t	2) Provision of personal protective								
1	equipment to employees with								·
	potential for an occupational								
	exposure as as determined by								
	job classification				 				
	3) A confidential medical								
	evaluation & follow-up care						·		
:	is offered to employees who								
	experience an occupational								
	exposure: a) Counseling				 	-			
	b) Testing of source individual						 		
	if allowable under state &/or								
	local law								
	c) Blood testing of exposed								
	employee with written								
	consent if medically								
	indicated								·
	4) Accurate, confidential & timely								
	documentation of:								
	a) Circumstances leading to								
	exposure				 				
	b) Routes of exposure							ļ	
	c) Medical follow up				 		-		-
	d) Opportunity for counseling						 	<u> </u>	-
	e) Other related interventions as indicated & necessary				1				
CII.7i	The organization demonstrates						ļ		
C11.//	compliance with its TB Exposure] .				
	Control Plan								
CII.7j	The organization demonstrates			<u> </u>	 	 	 	 	-
	compliance with its safety								
	program to monitor environmental				1				
	conditions for identifying								
	potential hazards/risks			-		1			•
CII.7k	A routine assessment is made of					+	1		
	the client's living environment to								
	identify & evaluate potential								
'	safety hazards related to the								
	physical space, as applicable	1						ŀ	

SITE VISITOR DATA COLLECTION WORKBOOK

EVIDENCE GUIDELINES	CITATION STATEMENTS
D = Documentation S = Survey O = Observation I = Interview	
D&I: Evidence exists that the	-
organization monitors and	
reports information related to	
adverse events. (CII.71)	
Reports document data on adverse events that predispose the	
organization to real or potential	
liability.	
Data are collected within	•
30 days of an event	
 Data are analyzed within 	
60 days of the event to	
determine underlying	
factors leading to the adverse event	
Performance	
Improvement processes,	
as applicable, include	
evidence of organizational	
changes subsequent to an	
adverse event	
(CII.71)	
D: Medical Device Act reports, as applicable, are on file in the	
Organization and include	
validation of submission to the	
FDA. (CII.7m)	
I&O: Staff demonstrate knowledge of	
and compliance with the	
organizational infection control practices and procedures. (CII.7n)	
D: Examples of complaint	
documentation logs. (CII.8a)	
D: Formal documentation of	
investigative findings and reports	
as applicable. (CII.8a) D: Resolution information is	
documented as communicated to	
the complainant. The	
communication to complainant	
may be in writing or by telephone.	
(CII.8b)	
I: Staff describes an understanding of the complaint process. (CII.8c)	
the complaint process. (CII.6c)	

CI1.71	A system is in place for									
	monitoring & reporting									
	information related to adverse									<u></u>
	events that endanger the health &									
	safety of clients &/or employees	1								
)	& predispose the organization to									
	real or potential liability				-					•
	1) Adverse Events & Serious									
	Adverse Events are defined in									
	organizational policy					٠.,				
	2) Data for all events is collected/									· · · · · · · · · · · · · · · · · · ·
	analyzed/tracked/ trended as a									· · · · · · · · · · · · · · · · · · ·
										·
	part of risk management									
	3) Corrective actions are									ļ
-	implemented & evaluated as									
	indicated & necessary									
	4) Adverse event reports detail									
	each episode & are distributed									
	to advisory boards &						.			
	accrediting bodies as									
	applicable					-				
CII.7m	The organization demonstrates									
	compliance with its P & P's for									·
	the Medical Device Act (MDA)									
CII.7n G121	The organization demonstrates									
L105, 305	compliance with its infection									
L327	control P & P's:						ì			
C11.8	Glient family complaints/									
	concerns are ore sponded to &									
	resolved in a nimely-manner									
CII.8a	The complaint process includes									
	intake, investigation, corrective									·
G107	action as applicable, complaint									
	resolution, written reports,									
	organizational trending &									
	follow-up									
CII.8b	Resolution/outcome information									
	is communicated to the									
	complainant									
CII.8c	Staff are aware of organizational									
	mechanisms for receiving &									
	resolving complaints									
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TE VISITOR DATA COLLECTION WORKBOOK

EVIDENCE GUIDELINES	CITATION STATEMENTS
D = Documentation S = Survey	
O = Observation l = Interview	·
D: Policy, procedure and recruitment	
documents support a non-	
discriminatory approach to hiring.	
(CIII.1a)	
I&O: Interviews with staff and	
observation of client	
practice/service validate adherence	
to discipline specific practice	
standards and to regulatory	
guidelines and requirements	
specific to respective areas of	
responsibility. (CIII.1b)	
I: Staff confirm clear understanding of	
responsibilities and lines of	
authority. (CIII.1c)	
I: Management explains turnover rate	
variances as applicable, and	
describes impact on recruitment	
and retention activities. (CIII.1d)	
D: Employee records validate the	
opportunity for a formal exit	
interview for terminating	
employees in accordance with	
organizational policy and	
procedure. (CIII.1e)	
I: Employees validate receipt of	·
conditions of employment and	
describe the process for obtaining	,
personnel related information.	
(CIII.1f)	
D: Employee files are complete and	
current and include documents	
specific to CIII.1g. Evidence of	
verification of education/training	
may include copies of diplomas,	
transcripts or telephone validation.	
(CIII.1g)	and the control of th
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	t
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TP/A	ADEQUATE RESOURCES. HUMAN, FUNAINCIAL &												

	The organization has adequate-												
1.1	- & appropriate human resources												
	to nieet caseload & workload												
	demands			-				ļ					
CIII.la	A non-discriminatory recruitment									-			
	& selection process, as defined in P&P'S, is adhered to	-									,		
CIII.1b	Personnel are employed &							<u> </u>		-			
	assigned responsibilities												
G121	commensurate with their				,								
	education & experience												
CIII.1c	Job descriptions for each												
	employee category delineate lines												
	of authority & reporting												
	responsibilities, duties to be					1							
THE PROPERTY OF THE PROPERTY O	performed & educational &												
	experiential qualifications specific				-								
CIII.1d	to the position			<u> </u>		<u> </u>	<u> </u>						
CIII.ia	Employee turnover rates are					Ì							•
	monitored, tracked & trended as applicable												
CIII.1e	The opportunity for exit					<u> </u>							
0.1.1.1	conferences are:									'			
	1) Offered to terminating												
	employees as applicable												
	2) Documented & trended as												
	applicable						ļ						
CIII 1f.	Personnel policies/conditions of												
1	employment are provided to					1							
	employees::)
	1) At time of hire and 2) Thereafter, as updates/revisions			1									
	are needed												
CIII.1g	Evidence of the following			 	l								
	employee information is			1									
	maintained in accordance with												
	organizational policy & regulatory												
	guidelines:							ļ	<u> </u>				
G141	1) Individual job qualifications						ļ	ļ	ļ	-			
	2) Verification of												
	education/training					 	-	ļ	 	-			
	3) Certification for specialty areas							}		1			
	of practice as applicable 4) Statement of formal training for			<u> </u>			-	+	-	-			
	non-professionals		,					1					
	5) Two (2) reference checks						-	+	+	1			
	6) Pre-employment interview(s)	<u> </u>	 			 	1	 	-	1			
G141	7) Current license/certification as	 				+	1	+	1	1			
L174	applicable												
	8) Validation of competency skills		 				1	1	1	1			
	testing as applicable												
G211, 212	a) Time of hire					1.1				7.			
	b) Annual	ļ								1			
L			<u> </u>		<u> </u>							 	

ITE VISITOR DATA COLLECTION WORKBOOK

EVIDENCE GUIDELINES	CITATION STATEMENTS
D = Documentation S = Survey	
O = Observation $I = Interview$	
O: Specified personnel documents are secured in accordance with	
organizational policy. (CIII.1h)	
D: Annual evaluation form addresses	
elements of CIII.1i as applicable	
for the job category.	
I: Sample of employees and	
supervisory staff personnel records	
confirm adherence to the annual	
evaluation process. (CIII.1i, 1j)	
D: A written plan details the	
orientation of new personnel and	
for personnel assigned to a new job	' I
classification. Components of the	
orientation plan may include	
mission and purpose of the	
organization, table of organization,	
lines of authority and	
responsibility, hours of work, job-	
related responsibilities, and personnel policies. (CIII.1k)	
I: Recent hires describe their	
orientation as comprehensive and	
pertinent to meeting job	
responsibilities. (CIII.1k)	
I: Staff assigned to a new job	
classification describe their	
orientation to the new	
responsibilities. (CIII.1k)	
7 top ond:2221000 (
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	9) Validation of performance												
G214	evaluation at end of probation												
	& annually												
	10) Validation of malpractice												
1	coverage for independent contractors	-											
	11) Validation of completion of	1				 					:		
	orientation (new & reassigned				-								
	personnel)						1						
	12) Validation of signed & dated										•		
	confidentiality statements												
	13) Validation of in-service/										,		
	continuing education					-							
	participation as applicable						ļ		٠				
	14) Validation of exit interview as												
	applicable 15) Miscellaneous items per state,				ļ						•		
	federal or organizational										•		
	requirements												
	16) Criminal background checks										•		
	in accordance with							-					
	organization P & P and local							'					
	and/or state law												
	17) Immigration & naturalization statement (I-9)												
CIII.1h	Specified personnel documents												
	and employee health reports may												
	be retained in separate files per				1								
	organizational policy												
CIII.1i	An annual written performance												
1214	evaluation process is completed												
	on all employees by their												
	respective supervisor & includes: 1) Supervisor assessment of			****									
,	employee performance in												
	accordance with established												
	criteria (Job Description)						`						
	2) Achievement of previously												
	established goals												
	3) On-site evaluation												
•	reports/competency testing for clinical/field/service staff												
	4) A signed, dated validation of						7						
	the evaluation process by the				er er er er er er er er er er er er er e	1000							
	employee & employer				-								
	representative												
CIII.1j	An annual performance evaluation												
}	process provides an opportunity for active participation by												
	employees through:												
	1) Employee development						<u> </u>						
	planning/new goal setting												
	2) Employee response to					<u> </u>							
	evaluation												
* CIII.1k	A written plan details the					· ·						•	
CHLIK	orientation process for all new &												
140	reassigned employees which												
.161	addresses applicable elements pertinent to each job classification												
	periment to each job classification												
					<u> </u>	<u> </u>				 			

TE VISITOR DATA COLLECTION WORKSOOK

EVIDENCE GUIDELINES	CITATION STATEMENTS
D = Documentation S = Survey O = Observation I = Interview	
I: Staff validate receiving applicable	
hours of in-service programming and describe the types of	
experiences available to them. (CIII.1l)	
O: Federally required in-services include OSHA mandated. Staff	
Development opportunities may	
include: independent study, satellite learning, specialized	
conferences, formal courses of study and mentoring. (CIII.11)	
D&I: Policy and managers describe the process for assuring that	
personnel are identified. Service contracts with organizations detail	• -
the process that sub-contract	
organization will assure sub- contract organization	
identification of staff. (CIII.1m)	
D: A review of randomized sample of	
written contracts for the provision of care, services and/or products	
validates adherence to CIII.2,a,b I: Contract manager or other	
designated party describes the ongoing management and control	
of contractual agreements. (CIII.2a)	
an illustration of the control of	
	·
	ε
	-

CIII.II	The												
G134, 178,	The organization shall provide in-								1				
G189, 192,	service and staff development as	ļ.											
	needed and as required by												
7,00, 215	local/state/federal regulations &					,							
40, 161	national and/or professional												
1 .40, 101	standards as applicable	١.											
CIII.1m	Personnel are provided with	 			 		 						
1	identification badges or are												
		١,						1					
į	identified as working for the											•	
TO COMPANY OF THE PROPERTY AND THE PARTY AND	organization												
C111.2	Formal written contracts.												
	executed by the primary												
	organization with other							l:					
	professionals &/or other entities												
	for the provision of care services												
	& products to clients of the												
	primary organization, detail			-									
	specific responsibilities of the												
CIII.2n	parties involved		1										
G146	Written service contracts with												
0	individuals &/or other entities are							1					
L115, 117	signed & dated by authorized												
L126, 189	principals of each party & are												
	reviewed annually												
CIII.2b	The executed document stipulates												
	the terms of the contract which												
	includes:												
G123, 142	1) Specific services/products to be												
L118	provided												-
	2) Contractor is required to adhere												
G142	to applicable primary												
L124	organization's P&P's												
	3) Assurance by the contractor of												
G142	the education, training,												
G 231													
	qualifications, & identification												
L123	of personnel designated to							1					
L189	provide care, services &						1	l.					
	products												
G1.45	4) Mechanisms for the contractor												
G142	parties to participate in								,				
L120	Performance Improvement								İ				
	activities as applicable												
	5) Procedures for the												
G142	documentation & submission of						-						
	documented notes that verify												
L122	the provision of												
1122	services/products in accordance												
	with the written service contract												
							<u> </u>		ļ				,
	6) Procedures for the submission												
L124	of bills & related information									-			
L125	& reimbursement for care,												
	services & products provided												
	7) Effective dates of the contract,									1			
5	including terms of renewal								İ				
	&/or termination												
	oo, or community									[
								ì	1	1			

EXTREMOS CUIDEL INEC	CITATION STATEMENTS	
EVIDENCE GUIDELINES D = Documentation S = Survey	CHAITON STATEMENTS	
O = Observation S = Survey O = Observation I = Interview		
D: Organizational policy and		
procedure detail the fiscal		
activities and responsibilities of the		
organization. (CIII.3a)		
I: The chief financial manager		
confirms credentials and	•	
experience background for the		
responsibilities assigned and		
describes the budget planning		
process. (CIII.3b) D: Governing Body minutes confirm		
approval of budgets and other		
financial agenda items referred to		
the Governing Body. (CIII.3c)		
D: The organization has current		
operating budget and capital		
expenditure plan. (CIII.3d)		
D: Financial, statistical and		
productivity reports are used to	6	
facilitate oversight of the		
organization's operations.		
(CIII.3e)		
I: The chief financial manager		
describes the use of financial,		
statistical or productivity reports. (CIII.3e)		
I: The chief financial manager		
validates the adequacy of		
insurance coverage. (CIII.3f)		
D: Review of annual financial review		
validates that the review was		
conducted by an organization		
external to the organization within		
the most recent twelve month		
period. (CIII.3g)		
75 77 L1 4 14 14 14 14 14 14 14 14 14 14 14 14		
D: Financial reports detail the information used to measure	·	
operational performance.		
(CIII.4a,b)		
I: The chief financial manager or other		
designated party describes the		
effectiveness of the financial		
management information systems,		
the types of reports generated and		•
their use, and internal financial		
controls. (CIII.4a,b,c)		
- · · · · · · · · · · · · · · · · · · ·		

C1II.3	The organization's sources of						,					
	financial support are managed & monitored on an ongoing											
	basis to ensure the availability											•
	of adequate funding											
CIII.3a	Financial P&P's govern fiscal											
L108, 125	activities of the organization											
CIII.3b	The chief financial manager has											
	the appropriate qualifications,											
	credentials & expertise to oversee,											
	manage & direct the fiscal										•	
	operations of the organization										•	
CIII.3c	Major participants in developing											
	& monitoring the budgetary											
G147, 148	process include the GB, the chief											
	executive, the chief financial				-							
	manager, program directors & other designated staff as											•
	appropriate											
CIII.3d	The operating budget & operating							-:				
	capital expenditure plan is											
G147, 148	developed using methodologies											
G147, 146	commensurate with the scope &	-										
	complexity of the organization's											
	services, programs, & products &											
	is used to forecast financial &						:					
	operating successes & challenges				<u> </u>	ļ						
CIII.3e	Financial management tools are											
	used to provide operational feedback to administrative &											
	management personnel, financial											
	committees & the GB											
CIII.3f	Adequate insurance coverage is	-										
	maintained											
Clll.3g	An annual external review is											
	required & conducted									_		
CIII.4	A financial management											
	-information system is used to											
	document and monitor all						ļ					
	finalicial components and											
	provide appropriate and timely are not to all levels within the	,										
	organization/s											
CIII.4a	The financial reporting system		<u> </u>			<u> </u>		<u> </u>				
	produces detailed data regarding											
	actual transactions specific to											*
	care, services & products provided						1					
	by each program including											
	site/location activity						ļ		-	4		
CIII.4b	Periodic financial statements											
	contain key financial indicators &	/										
	show a reasonable match between											
	revenue & expense line items						.]'	1				
		L	L	<u> L.</u>								

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	EVIDENCE GUIDELINES	CITATION STATEMENTS
	D = Documentation S = Survey O = Observation I = Interview	
D:	Organizational financial	•
	procedures used for internal control may include segregation of	
	duties, reconciliation of control accounts, approval levels for	
	disbursements and adjustments, collection of accounts receivable,	
	budgeting, receipt of funds,	
	disbursement of funds, cash and asset account reconciliation and	
I: :	cash management. (CIII.4c) Financial/billing staff confirms	
	timely billing procedures ongoing monitoring of accounts receivable,	
	implementation of collection efforts as appropriate, and	
	adherence to accounts receivable guidelines. (CIII.4d)	
D:	Financial reports include payroll	
	and vendor disbursements in accordance with CIII.4e.	
	· •	
•		
	:	
		y Control Control
		,

CIII.4c	Internal financial controls are in											
	effect										-	
Ì	1) Internal audit procedures &											
	annual review of budget are						.	l				
149	conducted											
	2) Adherence to organizational				.				» ·	•		
GVIII 44	financial P&P's is monitored Reimbursable services are billed	-										
CIII.4d	Reimbursable services are billed									8		
	on a timely basis in accordance											
	with designated fee structures &							Ì				
CIII.4e	are monitored, tracked & aged Payroll & vendor disbursements	-										
CIMAC	are recorded & processed in a											
	structured & timely manner											
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TE VISITOR DATA COLLECTION WORKDOOK

	EVIDENCE GUIDELINES	CITATION STATEMENTS
	D = Documentation S = Survey O = Observation I = Interview -	
D:	Applicable statements indicating	
	compliance with OSHA, CDC,	·
	ADA, are available and may	
	include:	
	1) Fire drill and health	
	inspection reports indicate	
	compliance.	
	2) Certificates of occupancy are	
	posted in accordance with	
	local requirements.	
	3) Fire and emergency exits are	
	clearly detail areas of	
	entrance and egress.	. !
	4) Hazardous area access is	
	controlled.	
	5) Hazardous chemicals and	
	solutions are properly	er pr
	labeled and kept in locked	
	storage.	
	6) Adequate space and privacy	
	is provided to employees and	·
	clients receiving services.	
	7) Facilities are barrier free	
	and/or special arrangements	
	are made to provide access as	
	indicated and necessary.	
	8) Safety and security	
	procedures for employees are	
	implemented as necessary. (CIII.5a)	
ο.	Tour of facility validates	
O:	compliance with OSHA, CDC, and	·
	ADA guidelines and applicable	
	local requirements. (CIII.5a)	
	toom requirements. (CIII.ou)	
D&	I: MIS manager or other	
	designated party explains and	
•	demonstrates how data are	
	collected, processed and secured	
	on the off site. (CIII.6a)	
I : 1	Management describe how	
	information system is used to	
	ensure organizational	·
	accountability. (CIII.6)	
	•	
		r .
	·	

СШ(5)	Physical facilities are adequate to support the operations								
CIII.5n	to support the operations Physical facilities meet the								
	OSHA (Federal/State), CDC,			·					
) , G.18	ADA &/or state or local regulations for environmental						-		
L124	protection & safety of employees			•					
L305	& recipients of service		·						
C111.6	A management information system is utilized to ensure accountability at all levels of the organization						-		
CIII.6n	A manual or automated system utilizes established standards &								
	defined data elements for the			٠					
	collection & processing of								
	information	•							
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SITE VISITOR DATA COLLECTION WORKBOOK

EVIDENCE GUIDELINES	CITATION STATEMENTS
D = Documentation S = Survey O = Observation I = Interview	
I: Management and staff describe the	
planning process. (CIV.1a) 1&O&D: The assessment of the	
strengths, weaknesses,	
opportunities and threats may	
include the following components:	
1) Asses and analyze service area	
demographics.	
2) Maintain current knowledge of	
organization's market penetration.	
3) .Identify new and/or changing	
consumer and community	
needs.	
4) Collect data and information	
for analysis. 5) Garner input from all levels of	
staff.	
6) Determine organizational priorities.	
(CIV.1b)	
I: The CEO and/or governing body	
representative describes the long term vision and goals for the	
organization. (CIV.1b)	
D: The organization provides evidence	
that a current annual evaluation was conducted timely and in	
accordance with its organizational	
policies and process. (CIV.2a)	
D: The annual evaluation report	
validates the inclusion of service/product, risk management,	
human resources and financial and	
operational components in the	
evaluation process. (CIV.2b)	
I: Administrative/management personnel describe how the	
complexity of the organization	
relates to data collection and	
utilization. (CIV.2b)	
D&I: Minutes and interview confirm that the annual evaluation report	
was presented to the appropriate	
advisory and governing bodies.	
(CIV.2d)	

	LOSC OBRAZISES BILION										
CUV											
CIVA	Strategic planning reflects the									•	
	organizational mission &	-									
	includes a comprehensive										
	evaluation of both internal &										
	external environments										
What was a state of the state o				· · · · · · · · · · · · · · · · · · ·							1
CIV.1n	Current budgetary, business &										
	marketing activities are integrated									•	
4	into the process			,							
CIV.1b	An assessment of the										
	organization's strengths,										
	weaknesses, opportunities &		,								
	threats is conducted on a periodic										
	basis									•	
CIV.2	Au annual evaluation of the										
	corganization provides the basis								-		
	Tor Tumne planning										
CIVA							ļ				
CIV.2a	Organizational policies drive the										
G242, 243	process for the annual program										
G242, 243 G249	evaluation by an authorized group					ľ					
راحين	& identify the components to be										
	evaluated							ĺ			
CIV.2b	The complexity of the										
C1 1 120											
G245	organization & the scope of care,									•	
G 249	services & products provided						1				
	define the parameters for data										
L142	collection & utilization and						ĺ	-			
	includes:					ĺ			:		
	1) Service/product data						i				
	2) Risk management data										
								-			
	3) Human resources data							Ì			
_ '	4) Financial data						<u> </u>				
CIV.2c	Variances from usual & expected										
	patterns of performance are	,									
	analyzed & explained						1				
CIV.2d											
G153, 154,	The Annual Evaluation Report is										
G246	presented to advisory & governing							ĺ			
L143	bodies as appropriate										
CIV.2e	The Annual Evaluation Report is										
	retained as an administrative										
G247	record										
										4	
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	organizaci decide existencia (n. 1900)						ļ				
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:						133					



PHARMACY STANDARDS OF EXCELLENCE 2004-2005 EDITION



SITE VISIT WORKBOOK

Site Visit Dates:	to	4
Name of Organization:		
Address:	Telephone:	
	Fax:	
	E-mail:	
		* .
Contact Person:		
Fitle:		
Medicare #	Medicaid #	
Other #		
Visit Type		
CTOP VICT	TOR CITATIONS:	
SILE VISI		
Commendations		
Former Required Actions	New Recommendations	
Met		
Continued as RA		
Continued as Rec	Modified CORE (√)	
Site Visitor Name	Signature	<u>Initial</u>

CHAP: 4/2005

CHAP PHARMACY STANDARDS 2004/2005 Evidence Guidelines Citation Statements SITE VISITOR DATA COLLECTION WORKBOOK

EVIDENCE GUID	ELINES	CITATION STATEMENTS	
	S = Survey		
	I = Interview		÷ .
i i i i i i i i i i i i i i i i i i i	- ·		
	£ 4ho		
D: A printed definition o organization's scope of	of products		
and services is availab	ole. (DI.1)		
D: Governing body minu	ites document		
actions taken on the	scope of		· · · · · ·
products and service (a) Review and appr	s statement:		
past twelve mont	ths.	÷ .	
(b) Revisions and up	dates as		
applicable.			
(DI.1a)			
I: Management and sta	iff describe the		
I: Management and sta process for making t	he scope of		
products and service	s statement		
available upon reque	est. (DI.1b)		
D: Required County/St	ate/Federal		
licenses, authority de and Medicare/ Medi	ocuments,		
reimbursement certi	fication (if		
applicable) are curr	ent as required.		
$(\widehat{\mathbf{DI.2a}})$			
	i linamaa		
Note: County/State s may include Se			
Occupational I		·	
(DII.2a7)	. *		
D: Review of recent fine	dings of other		
reviewing bodies con compliance. (DI.2a)	шиш		
computation (Dirac)			
D: The disclosure state	ment is current,		
signed and dated by	the chief		
executive and is on	ine. (D1.2D)		
5			

	PHARMACY STANDARDS	Visit	SS		Current Visi	t	COMMENTS		
		NM	-	NA	Met Com NVI	RA Rec			
CPA	A PARTICIPATION CONTROL OF THE SAME			1121					
DLI	A written statement by the Pharmacy Organization identifies the scope of products and services provided to clients.								
DI.1a	The scope of services statement is periodically								
	reviewed, revised and approved by the governing body but no less than every twelve (12) months.								
DI.1b	The pharmacy's scope of services statement is made available upon request to clients, referral sources and other interested parties.								
	The Pharmacy Organization has the structure and functional mechanisms necessary to accomplish its stated scope of services.				•				
DI.2a	The Pharmacy Organization has the legal authority to operate and is in compliance with local, state and federal regulations.						-		
	1) State Board of Pharmacy License								
	2) Business License								
	3) DEA Narcotic License			ļ					
	4) d/b/a, Trade Name registration, if applicable			ŀ			,		
	5) Tax ID number								
	6) Medicare & Medicaid provider numbers, where applicable								
	7) Specific county and state required authority								
DI.2b	The Pharmacy Organization is required to prepare and maintain a current written disclosure statement signed by the chief executive, addressing applicable elements as frequently as required by state regulations but no less frequently than every three years.								
	1) Names and addresses of individuals or corporations having a combined direct or indirect ownership or controlling interest of 5% or more in the organization								
And the second s	2) Names and address of subcontractors in which the organization has a direct or indirect ownership of 5% or more	1							
	3) Names and addresses of individuals, who are related as spouse, parent, child or sibling to individuals described in (1) and (2) above								
	4) Names and addresses of individuals in (1), (2) and (3) above with an ownership or controlling interest in a Medicare or Medicaid facility	17							

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	EXPORAGE CHÍDELINES	CITATION STATEMENTS
	EVIDENCE GUIDELINES D = Documentation S = Survey	
	O = Observation I = Interview	
D:	Minutes or other formal governing body documents reflect that the governing body authorized an	
	advisory committee. (DI.2c)	
	Note: Advisory Committee may be the governing body as a whole, a subcommittee of the governing body or a separate committee.	
ъ.	Membership in the advisory	
D:	committee includes a physician, a pharmacist, a registered nurse and at least one community	
	representative. (DI.2c)	
D:	Official documentation or minutes reflect annual review of policies and evaluation of the Pharmacy	
	program. (DI.2c)	
Ι:	Management and staff describe and cite examples of how current clinical and organizational data are assessed and used in revision of policies and practices. (DI.2d)	
D:	A current organizational chart is available and clearly delineates the lines of authority and	
	accountability for all organizational positions. (DI.3a)	
I:	Staff members are familiar with the	
	organizational chart and state their individual lines of authority and accountability.	
	(DI.3a,3b)	

	PHARMACY STANDARDS	Visit NM	22		Curren				COMM	TOTAL TO	
		14141		NA	Met Com	NM RA	Rec				
ematuaji() 2011-9620-9630-9640-9640-96	5) Names and addresses of officers, directors or partners							-			
	6) The circumstances of any criminal offense conviction involving Medicare/Medicaid programs on in (1), (2) or (3) above and/or, on the part of any managing employee of the organization										
	7) The dates of any changes in ownership or control during the previous twelve (12) months										
	The dates of anticipated changes of ownership or control in the next twelve (12) months										
DI.2c	An Advisory Committee of professionals is authorized by the governing body to advise the organization on policies and to evaluate the Pharmacy Program.	-									
	1) Responsibilities of the committee include establishment and annual review of pharmacy policies and participation in the annual evaluation of the Pharmacy program.										
	2) Membership of the committee includes a physician, a pharmacist, a registered nurse and at least one community representative who is not an employee										
No. 1 and Manager Shaft year on Land America	3) Committee meeting minutes reflect the committee's fulfillment of its responsibilities	and the second or				1					,
	4) The Advisory Committee meets at least once annually.										
DI.2d	Systems exist for obtaining and integrating the mos- current information into the professional practice to be used in planning, evaluation and decision making in all aspects of the program	0							A seem of	* · · • ·	
D1.3	Intra-organizational relationships of the Pharmacy Organization are clearly defined in writing.										
DI.3a	A current organizational chart illustrates the lines of authority and accountability for all administrative, professional, technical, clinical and clerical personnel.										
DI.3b	The complexity of the Pharmacy organization's administrative structure is appropriate for efficient delivery of product and service.	ıt									

	EVIDENCE GUIDELINES	CITATION STATEMENTS
	D = Documentation S = Survey	
	O = Observation I = Interview	
		•
D:	Pharmacy Program Director's	
	resume, diploma, reference checks and current professional	
	license verify compliance with	
	requirements for the position.	
	(DI.4a, DI.4b)	
	Note: The Pharmacy Program	
	Director may be a regional position	·
	in multi-state organizations. In that	
	instance, the Program Director would	
	have a current active Pharmacist license in a state. The Pharmacist in	
	Charge at the specific site will have	
	an active Pharmacist license in that	
	state. The Pharmacy Program	
	Director and the Pharmacist in Charge may be the same or separate	
	position in the organization	
	·	
I:	Pharmacy Program Director	
	demonstrates knowledge of local, state and federal pharmacy	
	regulations. (DI.4b)	
	J	
D:	The Pharmacy Program Director's	
	job description and/or policies include responsibilities as specified	
	in elements 1-11, or the	
	responsibilities are clearly delegated	
	in writing to other specific positions.	
	(DI.4c)	and the state of t
I 8	c O: The Pharmacy Program	
	Director demonstrates	
	understanding of his/her role.	
	(DI.4c)	
	•	
1		

	PHARMACY STANDARDS	Visit	SS		1	Curren	t Visit		COMMENTS
		NM		NA	Met	Com	NM RA	Rec	
DI.4	Authority and responsibility for the overall executive management of the Pharmacy Organization is vested in qualified individuals:					·			
DI.4a	The Pharmacy Program Director is a graduate of a pharmacy program accredited by the American Council of Pharmaceutical Education or has passed a Foreign Pharmacy Graduate Equivalency Examination given by the National Association of Boards of Pharmacy, is currently licensed as a Pharmacist in the state.								
DI.4b	A qualified pharmacist with appropriate knowledge, expertise and experience is responsible for the management, direction, coordination and general supervision of all professional services.								
DI.4c	The Pharmacy Program Director is responsible for the following areas either directly or by clear delegation:								·
	Organizing and directing the Pharmacy program's operations to assure the availability of services and products provided								
	2) Assuring adequate inventory of pharmaceuticals and supplies necessary to compound and dispense prescriptions appropriately, including periodic inspection for outdated products.	111111111111111111111111111111111111111					A		
	Assuring all equipment utilized in the delivery of the organization's products and services is properly maintained								
	4) Assuring pharmacy services are provided in compliance with applicable laws, regulations, accreditation standards and ethical standards of practice								
	5) Assuring adequate and appropriate staffing, including recruitment, orientation, in-service education and completion of annual performance appraisal								
	6) Coordinating with other program areas and managers as appropriate, consistent with organizational structure								
manual Namandalas I o care (nama	7) Assuring the implementation of a pharmacy performance improvement program including evaluation of the home pharmacy program service								

VIDENCE GUIDELINES	CITATION STATEMENTS
= Documentation S = Survey = Observation I = Interview	
Vritten policy and procedure lefines assignment of dministrative responsibilities in he absence of the Pharmacy rogram Director. (DI.4d)	
Designated alternate to the Director inderstands his/her role and describes experiences specific the alternate roles. (DI.4d)	
DI.4 may appear to be a duplication of CI.4; however, CI.4 pertains to the CEO of an organization, and DI.4 pertains to the Pharmacy Program Director, which may be the same or separate position in the organization.	
Policies reflect the current practice, professional standards of service, and scope of service. (DI.5a)	
Pharmacy administrative policies and procedures at a minimum address items 1-4. (DI.5b)	
Pharmacy operational policies and procedures at a minimum address items 1–25. (DI.5c)	
Policy is available and includes temperature, light and security. (DI.5c.1)	
Policy is available when the pharmacy has a contractual relationship with a nursing agency. (DI.5c.8)	

	PHARMACY STANDARDS	Visit NM	SS	-		Curren				COMMENTS	ŀ
	8) Assuring Drug Control system consistent with policies and regulatory requirements	-F13434 prints would be Manis 400	1 . 1 mart 154 707 134) 119	NA_	Met	Com	NM B	A Rec			
	9) Assuring Drug Dispensing system consistent with policies and regulatory requirements										
	10) Assuring appropriate pharmacy supervision at all times	**************************************									
	11) Assuring safe and appropriate service policies are developed and implemented	•									
DI.4d	A qualified individual is designated in writing to act in the absence of the Pharmacy Director.										
DHS	Pharmacy policies and procedures reflect an emphasis on quality and ethical practice, relate directly to the scope of the Pharmacy program, and ensure client rights, and ethical standards of business and clinical practice.										A STATE OF THE PARTY OF THE PAR
DI.5a	Organizational literature, policies and procedures accurately reflect the current practice, current professional standards of service and scope of the Pharmacy program.					. See					
D1.5b	procedures include:										
	Regulatory Compliance Capital Short-fall Contingency Plan										
	3) Pharmacy Reference Materials 4) Annual Evaluation						_		_		
DI.50	Pharmacy Program operational policies and procedures covering the scope of services provided are developed and include at a minimum:							Mariano de la constanta de la			
	Storage of final pharmaceutical products First dose new drug administration								-		
	3) Handling investigational drugs								1		
	4) Client/caregiver instruction 5) Timely assessment of client eligibility and provision of service										
	 Notification of referral source if client does not meet admission criteria 										
	7) Delivery of services/products, as applicable		_	_							
	8) Contents, dispensing and maintenance of infusion emergency kits										
j	9) Acquisition, storage, disposition & dispensing of controlled substances	3						***			
	10) Selection, maintenance, use & control of infusion control devices for drug administration, a applicable	s						CLEANING PALING ALL PARISONS AND AND ADMINISTRATION			
	11) Client identification confirmation										

	EVIDENCE GUIDELINES	CITATION STATEMENTS	
	D = Documentation S = Survey		
	O = Observation $I = Interview$		
D:	Pharmacy operational policies and procedures at a minimum address items 1–25. (DI.5c)		
D:	Pharmacy clinical policies and procedures at a minimum address items 1 –6. (DI.5d)		
D:	Pharmacy quality improvement policies and procedures at a minimum address items 1-4. (DL5e)		
D:	Written policy is available for first dose drug. (DI.5f)		
	•		
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		Single Control of the	
			_
			_
			_
			-

	PHARMACY STANDARDS	Visit NM	SS		Curre	ent Visit	COMMENTS
				NA	Met Com	NM RA Rec	
	12) Availability of latex-free supplies						
	13) Prescription labeling						•
	14) Materials/Inventory Management						
	15) Equipment cleaning, testing and tracking		ļ.,				
	13) Equipment clouding, costing and states						
,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,	16) After Hours Coverage						
	17) Dispensing Records						
	18) Sterile Admixture Procedures for monitoring	A. H. H. H. H. H.					
	for medication errors, surface testing,						
	environmental air sampling and product sterility						·
				ļ			
	19) Preparation of injectables from sterile						
	solutions			-			-
	20) Preparation of injectables from non-sterile powders						
	21) Preparation of respiratory drugs from non-		-	1			-
	sterile powders						
	22) Clinical competency testing						
,	23) Competency testing of sterile product						
	preparation			-	_		
	24) Medication Error		_				_
	25) Recall			_			_
DI.5d	Clinical policies and procedures consistent with						
	professional standards of practice are developed			-			
	and include at a minimum the following:						
	1) Client Assessment			-			uret .
	2) Medication Assessment			_			
	3) Drug Profile Review			_			acces
	4) Care Planning, as appropriate		_				_
	5) Development of a comprehensive care plan						
	C) Citated monitoring		-	-			
57.5	6) Clinical monitoring Quality Improvement policies and procedures	-	_				
DI.5e	consistent with professional practice and regulatory	,		-			
	mandates are developed and include at a minimum	:					
1							
	1) Performance Improvement Plan						
	2) Structure and routine maintenance of						
	compounding areas						
	3) Maintenance of Laminar Flow Hood						
	4) Infection control, safety for preparation,						
	dispensing, disposal of pharmaceuticals						
DI.5f	Policies identify when a physician or other qualifie	d					
	professional is required to be present for the						
	administration of the first dose of a new drug to						
	detect, monitor and respond to adverse drug						
	reactions.						

EVIDENCE GUIDELINES	CITATION STATEMENTS
D = Documentation S = Survey	
O = Observation I = Interview	
D: Meeting minutes document	
discussions of and actions taken by	
the group, as applicable. (DI.6a)	
I &O: Staff demonstrates knowledge of	
and compliance with reimbursement and regulatory	
guidelines. (DI.6b)	
I: Pharmacy Director/pharmacists describe the process for	
assuring that clients are fully	
informed and provide written consent prior to participating in	
research or investigational studies.	
(DI.7a)	
D: Written contract or agreements	
pertaining to Pharmacy educational experiences for non-	
employees (i.e., students)	
exist as applicable. (DI.7b)	
D & I: Documents and interviews	
validate that current research	
initiatives exist as applicable. (DI.7c)	
D & I: Pharmacy employees publish research findings as applicable.	,
(DI.7d)	

	PHARMACY STANDARDS	Visit NM	SS		Curr	ent Visit		COMMENTS	
		11112		NA	Met Com	NM RA	Rec		٦
DI.6	The Pharmacy Organization's business and clinical activities are conducted according to ethical standards.							•	
DI.6a	A designated and qualified group of professionals/individuals address ethical issues relating to the business and clinical practices of the Pharmacy Organization. The issues include but are not limited to:	and an analysis of controls	-	The state of the s					
	1) Care delivery issues			-					
	2) Product and service related issues			ļ			_		
	3) Billing and collecting issues		ļ	ļ			_		
	4) Medical necessity authorization issues		ļ						
	5) Statistical data trending and tracking issues								
DI.6b	Staff are knowledgeable about and carry out their responsibilities for providing products and services in accordance with reimbursement and regulatory guidelines.	-							
DI.7	The Pharmacy Organization contributes to the development and expansion of knowledge in Pharmacy practice, as appropriate.								
DI.7a	A Pharmacy Organization participating in research or investigative studies ensures that clients are fully informed and provide written consent.	,							
DI.7b	Arrangements for student education experiences are formalized in written contracts or agreements that specify the responsibilities of the Pharmacy organization and the educational institution								
DI.7c	The Pharmacy organization demonstrates a positive attitude regarding research initiatives and consider requests for research in the area of pharmaceutica practice as appropriate.	s						9	
DI.7d	The Pharmacy organization encourages the publication of significant outcomes related to the management and practice of pharmacy.								

EVIDENCE GUIDELINES	CITATION STATEMENTS
D = Documentation S = Survey	
O = Observation I = Interview	
D: Current Public Disclosure policy	
includes the element of DII.1a,	
if applicable, in addition to the elements of CII.1a. (DII.1a)	
D: The Client Bill of Rights statement and/or other admission	
and/or other admission documents includes elements of DII.1b in addition to the	
elements of CII.1b. (DII.1b)	
D: Record review confirms that the Client Bill of Rights is signed	
by the client or client representative and is filed in the	
record. (DII.1c)	
O: Observation of the open door	
pharmacy validates that the Client Bill of Rights is posted in a public	
area. (DII.1d)	
D: Record review validates that pharmacy products and services	
are provided to clients consistent with the organization's stated	
scope of service. (DII.1e)	

	PHARMACY STANDARDS	Visit NM	SS		Curre	nt Visit	COMMENTS
	VIDEO CONTRACTOR OF THE STATE O			NA	Met Com	NM RA Rec	
DIN. 1	QUALITY OF SERVICES The Scope of Services drives the activities of the Pharmacy Organization and ensures public disclosure, client rights, and ethical standards of business and clinical practice.						
DII.1a	The written public disclosure policy makes the Annual Report for Corporations, if applicable, available to the public on request.						
DΠ.1b	A written Client Bill of Rights statement or other written admission documents are provided to the client or the client's representative at the start of care or at the time of initiation of care and include the right to be fully informed of:						
	Services and products being provided						
	2) Organization's ownership and control						
	Names and qualifications of individuals providing products and services						
	And the right to:						
111111111111111111111111111111111111111	4) Participate in one's own care						
	5) Continuity of products and services						
	6) Education about the products and services to be provided	·					
1114/processor ()) montpool	7) Refuse part or all of the products and services to be provided			_			-
	8) Receive products and services in a timely manner and in accordance with organizational policy						
	9) Be referred to another organization						
	10) Be free from abuse or exploitation of any kin			_			
	11) Receive information, both verbal and written in an understandable format.						
DII.1c	The Client Bill of Rights is signed by the client or a representative of the client and made a permanent part of the client's record.						
DII.1d	For clients receiving open door pharmacy services, the Client Bill of Rights is posted in a public area accessible to those clients.					a de la constanta de la consta	
DII.1e	The Pharmacy organization's products and service are provided in accordance with the organization's scope of services.						

	CITATION STATEMENTS
EVIDENCE GUIDELINES	CITATION STATEMENTS
D = Documentation $S = Survey$ $O = Observation$ $I = Interview$	
D: Record review validates that pharmacy products and services are provided to clients consistent with the organization's stated scope of service. (DII.1e)	
I & O: Interview and observation of practice confirms that the pharmacy organization is providing services as defined in DII.2a.	
D: Job descriptions and/or other policies identify duties and responsibilities of each discipline, which are consistent with national practice standards. (DII.2b)	
I & O: Interviews and direct observation of staff in practice confirm staff understanding and fulfillment of responsibilities. (DII.2b)	
D: Clinical record documentation by respective disciplines verifies fulfillment of assigned responsibilities. (DII.2b)	
and the state of t	

	PHARMACY STANDARDS	Prior Visit NM	SS	Current Visit	COMMENTS
-an article 19 and 14 March 1941 115	1) Statistical reports confirm that products and services are provided consistent with the Pharmacy organization's scope of services.			NA Met Com NM RA Rec	
	2) Staff at all levels are knowledgeable about and support the Pharmacy organization's mission and scope of services.				
DIL2	Pharmacy services are provided in accordance with organizational policies and procedures, to clients in their place of residence, and may include dispensing at the pharmacy site, transported delivery to home/client site or mailed delivery.				
DII.2a	Pharmacy services include but are not limited to:				
	Interpretation and evaluation of the prescription order				
	2) Drug product selection, compounding, dispensing, storage				
,	3) Distribution of drugs and devices				
	4) Advising the prescriber and other health care professionals, the clients and/or caregiver as to therapeutic actions, utilization and possible adverse reactions and interactions in order to encourage a positive client outcome.				
DII.2b	Pharmacy services are provided by or under the direction and supervision of a qualified pharmacist.				
	Professional pharmacy service is provided by a registered pharmacist and include:				
	(a) Overseeing the drug control system including:				·
	Receipt of prescription drugs and prescription orders				,
	2) Storage of medications				
	3) Packaging of medications				
	4) Preparation and dispensing of prescriptions				
	5) Labeling				,
	6) Preparation of prescriptions for delivery				
	(b) Instruction/counseling clients and caregivers regarding the specific drug therapy including possible adverse reactions and/or interactions				

EVIDENCE GUIDELINES	CITATION STATEMENTS
D = Documentation S = Survey O = Observation I = Interview	
D: Job descriptions and/or other policies identify duties and responsibilities of each discipline, which are consistent with national practice standards. (DII.2b)	
I & O: Interviews and direct observation of staff in practice confirm staff understanding and fulfillment of responsibilities. (DII.2b)	
D: Clinical record documentation by respective disciplines verifies fulfillment of assigned responsibilities. (DII.2b)	
I: Procedures for ensuring availability of drugs, supplies and equipment are described. (DII.2c)	
I: Job descriptions and/or policies include the indicated delivery personnel responsibilities. (DII.2d)	
I & O: Interviews and direct observation of delivery services during home visits confirms staff understanding and fulfillment of responsibilities. (DII.2d)	
I: Clients relate satisfaction with delivery services. (DII.2d)	

	PHARMACY STANDARDS	Prior Visit NM	SS		Current Visit		COMMENTS
				NA Met	Com NM RA	Rec	,
And and to a servery to make the control of the con	(c) Providing information regarding the safe and appropriate use of medications to other health care professional						
	(d) Identifying appropriate outcomes of drug therapy						
**************************************	(e) Consulting on drug therapy and coordinating with other health care professionals						
	(f) Monitoring and documenting ongoing drug therapy including the assessment of:						
	The therapeutic appropriateness of the choice of drug(s)						
	2) Therapeutic duplication in the client's drug routine						
	Appropriateness of the dose, frequency and route of administration						
	4) Adherence to drug regimen						
	5) Potential drug, food or diagnostic test interactions of disease limitations to drug use						
	Laboratory or clinical monitoring methods to detect drug effectiveness, side effects, toxicity or adverse effects						
	7) Preparing and maintaining clinical records						
	(g) Prescribing activities consistent with state/federal regulations.						
	2) Pharmacy technical services are provided by pharmacy technicians who have been trained for al tasks performed in compliance with state law, job description and organizational policy.	n				a Are area	
DП.2c	The Pharmacy Program provides pharmaceutical care, related supplies and equipment to clients.						
DII.2d	Delivery services are provided directly or by arrangement in compliance with laws and regulations and include:						
	 Safe and clean transport of pharmaceuticals and supplies to and from client homes/designated sites. 						
	Timely delivery of pharmaceuticals and supplies			100 mg			_
	3) Record keeping 4) Setting up equipment in client homes, if applicable						

	EVIDENCE GUIDELINES	CITATION STATEMENTS
	D = Documentation S = Survey	
	O = Observation I = Interview	
	U = Obbet vacion 1 = Interview	
I:	Procedures for ensuring availability	
1.	of drugs, supplies and infusion	
	devices when not available from the	
	organization are described.	
	(DII.2e, DII.2f)	
I:	Staff describe how necessary	
	services (pharmacy and	
	delivery) are made available to	
	clients at all times (on-call	
-	practices). (DII.3a)	
D:	Review of documents (complaint log, client satisfaction survey,	
	on-call logs) validate that response	
	times are consistent with policies	
	and meet client needs. (DII.3a)	
D &	& I: An on-call plan is available, and	
-	staff describe the on-call plan.	
	(DII.3b)	
O:	Testing of the on-call plan validates	
	that the organization is in	
	compliance with its on-call	
	coverage plan and policy.	
_	(DII.3b)	
I:	Client/family describes service availability after hours. (DII.3c)	
ъ.		ě
D:	are available and include items	
	1-3. (DII.3d)	
	1 2. (2 = 1.2)	
D:	Written policy identifies admission	
	criteria and referral process,	
	including when the organization	
	does not provide the needed	
	product or service. (DII.4a)	
D	Policies and procedures define the	
	responsibilities of the pharmacists, and record review confirms	
	documentation by the pharmacist.	
	(DII.4b)	
O		
0	fulfillment of responsibilities.	
	(DII.4b)	
D		
	the responsibilities for service	
	coordination. (DII.4c, DII.4d)	
		·
1		

	PHARMACY STANDARDS	Prior Visit NM	SS	Current Visit	COMMENTS
				NA Met Com NM RA Rec	
DII.2e	The organization has a process in place for assuring the availability of drug and supplies to clients in their designated sites not available from the organization.	·			
DII.2f	The organization has a process in place for assuring the provision of infusion devices to clients in their homes/designated sites when not available from the organization.				
D111.3	Clinical services and products are accessible and available to clients on an emergency basis 24 hours a day, 7 days a week.		-		
DII.3a	The Pharmacy Organization is accessible and responsive to the needs of Clients during normal work hours and after hours which includes:				
**************************************	Timely telephone response Timely on-site response, if indicated				
	Product and service delivery prior to scheduled use				
DII.3b	There is a plan for on-call coverage for after hours, weekends and holidays.				
DII.3c	Clients are informed of the process for accessing service during normal work hours and after hours.				
DII.3d	Written contingency plans delineate protocols for prioritizing delivery of product and services to clients including:				
	1) Disaster preparedness				
	2) Inclement weather events				
	3) Unexpected critical staffing deficits				
DIII.4	The Pharmacy Organization admits clients whose service needs can be met and ensures continuity of care/service through coordination of client services.				
DII.4a	Clients are admitted to service and continued on service, based on the reasonable expectation that their needs can adequately and safely be met by the program.	· ·			
DП.4b	A pharmacist assumes responsibility for planning, implementing therapy, evaluating the outcomes of therapy provided as applicable and documenting in the client record.	1			
DП.4с	Care is coordinated for each client by the pharmacist and includes at a minimum:				

	EVIDENCE GUIDELINES	CITATION STATEMENTS
	D = Documentation S = Survey	
	O = Observation I = Interview	
D:	Policies and/or procedures define	
	the responsibilities for service	
	coordination. (DII.4c, DII.4d)	
D:	Review of records confirms that	
	care coordination activities are performed. (DII.4c, DII.4d)	
	· ·	
	Note: Appropriate referrals involves	
	referrals for additional services as indicated. (DII.4d.4)	
D.	Client records document	
υï	interdisciplinary coordination as	
	appropriate. (DII.4e)	
1&	O: Pharmacists indicate how drug	: ·
	profile information is made	
	accessible to other appropriate professionals, the mechanisms for	
	coordination, the procedures for	
	coordinating delivery of medications, equipment and	
	supplies and that that they are	
	delivered and available as	
	appropriate. (DII.4e)	
D:	Client assessment policies and	
	record review validate the inclusion of specified items for all	
	pharmacies. (DII.5a)	
		*

	PHARMACY STANDARDS	Visit NM	SS		Curre	nt Visit		COMMENTS
				NA M	et Com	NM RA	Rec	
	Periodic verbal, telephone or electronic communication with other professionals involved in the care of the client							
	2) Timely documentation of the coordination of care activities							
	3) Involvement of the client/client representative when indicated							
DII.4d	For other than open door pharmacies, care coordination includes elements 1-3 of DII.4c plus the following additional components:							
	1) Initial assessment of the client, family and, if applicable, the home environment							
	2) · Development of a plan of care							
	3) Determination of expected outcomes		-					·
	4) Appropriate referral and follow up							
ļ	5) Implementation of the care plan							
			-					
	6) Ongoing evaluation 7) Plan of termination of care							·
DII.4 е	The pharmacist works collaboratively with other health care professionals to assure coordination of care.						41	
	1) The client drug profile information is available to professionals participating in the care of the client:							
	a) at a minimum, during operating hours for all pharmacies b) at all times, including after hours for							
	infusion pharmacies		_					
	2) The delivery of medications, equipment, and supplies is coordinated with other professionals involved with the care of the client to ensure that proper products and supplies are available when needed.							
DUS	The Pharmacy Organization defines the plan of care process, including assessments, physician oversight, dispensing and client training.							
DII.5a	An initial client assessment is made by the pharmacist prior to dispensing which includes at a minimum:							-
	 Name, address, telephone number, gender, age/date of birth of client 							
	2) Allergies/sensitivities of client							
	3) Medication Order							
	4) Physician name, telephone number							

	EVIDENCE GUIDELINES	CITATION STATEMENTS
	D = Documentation S = Survey	
	O = Observation I = Interview	
D:	Client assessment policies and record review validate the inclusion	
	of specified items in DII.5a and	
	DII.5b for infusion and long term	
	care pharmacies. (DII.5b)	
_	Medication assessment policy and	
D:	record review validate the inclusion	
	of elements 1-6. (DII.5c)	
D, I	&O: Interview, observation and record review confirm that client	
	assessments and medication	
	assessments are conducted prior to	
	dispensing. (DII.5a,DII.5b,DII.5c)	
D:	Policies establish mechanisms for	
D.	obtaining written physician	
	verification of and approval for	
	verbal orders. (DII.5d)	
D:	Record review documents that	
	required prescriptions were	
	received prior to dispensing	
	medications. (DII.5d)	
D:	Record review documents that	
	verbal orders are taken and signed	
	by the pharmacist prior to filling orders. (DII.5d)	
	orders. (DLL.5d)	
D:	Written policy is available and	Annual time of the contract of
	includes elements 1-11. (DII.5e)	
O:	Drug labels include the indicated	
0.	items. (DII.5e)	

,	PHARMACY STANDARDS	Prior Visit NM	SS			ent Visit	COMMENTS
				NA I	1et Com	NM RA Rec	
DII.5b	For infusion and long term care pharmacies, an initial client assessment is made by the pharmacist prior to dispensing which includes elements 1-4 of DII.5a plus the following additional components as appropriate:						
	Chief Complaint/Medical history/Diagnosis		-				
	2) Height and weight of client						•
	Client Infection, Sensitivities obtained as available	,,,,					
	4) Significant Lab Results			-			-
DII.5c	A medication assessment is made by the pharmacist prior to dispensing which includes at a minimum:						
	1) Potential drug interaction						
	2) Potential for poly-pharmacy		ļ				-
	3) Appropriate dose and frequency						
	4) Appropriate time of administration						
	5) Appropriate route and method of administration						-
	6) Appropriate infusion device of administration, if applicable						_
DII.5d	Pharmaceuticals are dispensed according to the prescription of a physician or physician designee legally authorized to prescribe in compliance with state regulation:						
	Written, verbal or faxed prescriptions are available to the pharmacist before dispensing the medication						
	2) Verbal orders taken from a physician or physician designee are recorded and signed by the pharmacist prior to filling the medication order						
DII.5e	All pharmaceutical products dispensed to clients are appropriately labeled according to state and federal regulations and, at a minimum, include:						
	1) Name, address and telephone number of the pharmacy						
	2) Date the prescription was dispensed						
	3) Expiration date of the medication						
	4) Pharmacy's prescription number						
	5) Client's full name						
***************************************	6) Name of the drug, brand, strength, if applicable, and the amount dispensed						
	7) Directions for use						
	8) Prescriber's name						
	9) Other pertinent information or cautionary labels						

	CITED EL TATEC	CITATION STATEMENTS
	GUIDELINES	OHITTOIN STILL
D = Documenta O = Observatio	tion S = Survey n I = Interview	
D: Plans of care a client and inch	re available for each	
(DII.5f)	·	·
include review	by physician may of orders, copies of nailed/faxed to	
plans of care r physician. (Dl	(I.5f.6)	
D: Written policy	and procedure cess for confirming	
client identific	eation. (DII.5g)	
explain the pr	ocess for confirming cation prior to	
dispensing. (D	II.5g) rocedures with	
specifications	detailed are available es for pharmacy	
infusion servi	ces. (DII.5h) iar with emergency	
procedures an	d provide examples priate use. (DII.5h)	
D: Drug informa	tion and instructional prepared for all types	
of products ar (DH.5i)	nd services provided.	
the client or c	cuments validates that aregiver was	
instructed in	self-administration of self-administration	
was indicated D: Client training	g/education is	
I & O: Clients un	(DII.5i, DII.5j) derstand their regimes.	
(DII.5i, DII.5		
appropriate	s document that clinical services were	
D: Client recor	clients. (DII.6a) ds are current and	
D: Client recor	nents 1-4. (DII.6a) ds document adherence	
and proced	ll written policies ures. (DII.6a)	
and include	profiles are current elements a– h.	
(DII.6a.1)		
,	,	

	PHARMACY STANDARDS	Visit NM	SS		Curre	nt Visit	COMMENTS
	10) Rate, route and method of administration			NA	Met Com	NM RA Rec	
	11) For IV mixture drugs, rate of administration and expiration date of the fluid						·
	A comprehensive plan of care is developed by infusion pharmacies which includes:						
	1) Establishment of Therapy Specific Goals						
	2) Determination of Expected Outcomes						
	3) Determination of Educational Needs						
	4) Establishment of Monitoring Plan						
	5) Determination of Achievement of Goals/Outcomes						
	6) Periodic Review by Prescribing Physician						
DII.5g	Client identification is confirmed prior to dispensing.						
DII.5h	For pharmacy infusion services, there are policies and procedures for emergency situations including, ordering of emergency kits with appropriate drugs by the physician and placement of these kits in the client's home, where appropriate.		AA T				
DII.5i	Drug information and instructional materials for administration are provided to the client or client caregiver at the time of dispensing.	1 - 1-1-1 (
DII.5j	Client training/education in self-administration is provided upon initiation of therapy, as applicable						
Durg.	Client records are maintained for each client and are utilized as a tool for coordination of services, as legal documentation of products and services provided and as a basis for billing and reimbursement procedures.						
DII.6a	Adequate and appropriate pharmacy records are maintained						
	1) Drug profiles are maintained for all clients and include the following information:						
	(a) Name, gender, birth date and weight (when appropriate)						
	(b) Address and client identification						
	(c) Allergies or sensitivities						
	(d) Diagnosis						
	(e) Current drug regimen	***************************************					on this late.
	(f) Dosages						
,	(g) Relevant clinical information regarding drug therapy						
	(h) Physician's name						

EVIDENCE GUIDELINES	CITATION STATEMENTS
D = Documentation S = Survey	
O = Observation $I = Interview$	
D: Pharmacy dispensing records include elements a-k. (DΠ.6a.2)	
D Records document adherence to first dose policy for new drug therapies. (DII.6a.2)	
D: Pharmacy dispensing records for other than open door pharmacies include items a-k of DII.6a.2 and elements a-d of DII.6a.3. (DII.6a.3)	
Note: Compounding instructions may be found in protocols, policies and/or specific instructional forms. (DII.6a.3c)	ę
Note: Documentation exists that a pharmacist oversees the process for dispensing, i.e., Pharmacist signature/initials on the label, on the compounding sheet, etc. (DII.6a.3d)	
D: Narcotic records include items specified. (DII.6a.4)	
I & O: Controlled substance records are maintained in compliance with state, federal and practice regulations. (DII.6a.4)	
D: Policy is current and describes signature authentication. (DII.6b)	
I: Records/system administrator describes the inclusion of the 9 items in the ongoing process of ensuring protection of data. (DII.6b)	
O: Pharmacy staff protect data consistent with policy and state law (DII.6b)	
I & O: A back-up and storage system is in place. (DII.6b)	

	PHARMACY STANDARDS	Prior Visit NM	SS		Curr	ent Visit	COMMENTS
				NA	Met Com	NM RA Rec	
	2) Dispensing records are maintained for						
	pharmaceuticals which include:						
	(a) Client's identification, name and address			ļ			
	(b) Name of medication						
	(c) Strength and dosage form	***************************************					
	(d) Quantity dispensed						-
	(e) Physicians' name						
	(f) Dispensing pharmacist/technician						1
	identification		,				
	(g) Prescription number			ļ			
	(h) Date dispensed						•
	(i) Directions for use						
	(j) Expiration date						
	(k) Number of refills authorized						
	3) Dispensing records for other than open door pharmacies are maintained for pharmaceuticals which include elements a-k of DII.6a2 plus the						
	following:	,					7
	(a) Lot number(s) of drugs						
\ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \	(b) Date of the addition(s) to intravenous admixture drugs						
	(c) Special compounding instructions as applicable						
	(d) Documentation of verification procedures						
	4) Controlled substance records are maintained in accordance with state, federal and practice regulations documenting that:			,			
	(a) A controlled substance inventory is performed in compliance with state or federal regulation.						
	(b) The pharmacist in charge is held accountable for the exact count of Schedule II pharmaceuticals						
	(c) The pharmacist in charge is held accountable for an approximate count of Schedule III, IV, and V pharmaceuticals.						
DII.6b	Automated clinical record systems ensure consistent and ongoing protection of data.						-
	1) Written policy describes signature authentication in accordance with individual state law						* 5
	2) Safeguards prevent unauthorized access to inputted information						
	Individual and protected access codes are assigned to individuals designated to perform data entry						
	4) Automated programs designate and control areas of access by authorized personnel based on a personal identifier and position in the organization						
		-					

	EVIDENCE GUIDELINES	CITATION STATEMENTS		1
	D = Documentation S = Survey			
	O = Observation I = Interview			ı
I:	Records/system administrator		•	ſ
	describes the inclusion of the 9			
	items in the ongoing process of ensuring protection of data.	•		ŀ
	(DII.6b)			
I:	The Pharmacy Director describes			
1.	the performance improvement			١.
	process for the pharmacy program. (DII.7a)			
	-			
D:	Evidence exists of utilization of performance improvement			
	findings to resolve problems and			
	improve quality of service/	,		
	products. (DII.7a)			
D:	The performance improvement			
	program includes items specified in DII.7a.			1
D:	The performance improvement plan includes items specified in			1.
	DII.7b.			
D:	Evidence exists of monitoring and			$\frac{1}{2}$
D.	analysis of findings as specified			
	in DII.7c.			
I:	Pharmacy Director and staff			1
	describe use of findings to identify problems and to improve			\downarrow
	performance. (DII.7c)			
	Staff orientation and in-service			1
D:	programs validate discussion of			4
	improvement program and			
	indicators. (DII.7d)			
				1
				4
				1
				4
				7
			-	_

	PHARMACY STANDARDS	Prior Visit NM	SS				ent Visit	COMMENTS
	5) The computer's internal clock designates date and time of entries			NA	Met	Com	NM RA Rec	
	6) Automated controls prevent a change in entry, allowing only corrections							
	7) Hardcopies of automated data are retrievable by designated personnel							
39.147-721 2111.000-0041130044441999999	8) A system for validation of inputted data is in place					.(
	9) An automated system for backup and storage of data is controlled, and the data is stored in a safe environmental place.							
DIII. 7	The adequacy, appropriateness, effectiveness and outcomes of products, services and supplies provided are routinely assessed.							
DII.7a	The Pharmacy Program has a formalized quality improvement program which is designed to:							-
	Identify desired outcomes Identify strategic and at-risk activities				-			
	3) Establish monitoring parameters for these activities							-
	4) Establish minimal standards or criteria to be met							
	5) Describe methods used to improve the quality of service and to achieve the desired outcomes.							
DII.7b	The Pharmacy Program has a written performance improvement plan which includes:							-
	Description of specific monitoring and evaluation activities							_
	2) Specification of how results are to be reported and evaluated							
	3) Identification of appropriate follow-up mechanisms when thresholds are exceeded							
	4) Delineation of individual responsibilities for each aspect of the program.							
DII.7c	The Pharmacy Program's performance improvement program includes but is not limited to:							
	1) Monitoring for medication errors							
	2) Monitoring and analysis of the findings from surface testing, environmental air sampling and encoproduct testing that includes sterility and pyrogens	1						
рП.7d	Staff orientation and in-service programs integrate a focus on quality.	}						

EVIDENCE GUIDELINES	CITATION STATEMENTS
D = Documentation S = Survey	
O = Observation I = Interview	
D & I: When the pharmacy is part of a larger organization, evidence is provided demonstrating integration of quality improvement plans. (DII.7e)	
D: Written policies exist and include items 1-10. (DΠ.8a)	
O: Observation of staff performing responsibilities confirms that staff adhere to infection control and safety policies and procedures. (DII.8a)	
D: Record review confirms that home environment assessments were conducted when indicated and that safety hazards were identified and precautionary instructions were provided to the client and documented. (DII.8b)	
D: Policy specifies types of staff designated to dispose of controlled substances. (DII.8c.1)	
D: Records confirm adherence to policy. (DII.8c.1)	
D: A Material Safety Data Sheet clearly outlines protocols for disposal of hazardous products. (DIL8c.2)	
O: The Material Safety Data Sheet is available in the pharmacy. (DII.8c.2)	
Note: The Material Safety Data Sheet information may be available	
on the pharmacy website as long as each pharmacy employee has access to the information.	

	PHARMACY STANDARDS	Prior Visit NM	SS				rrent Vi				COMM	ENTS	
				NA	Me	t Cor	n NM	RA	Rec				
DII.7e	The Pharmacy Program's performance improvement plan is integrated into the overall organizational quality improvement plan, as applicable.					7				,	·		
DIII.8	The health and well being of employees and clients is promoted and maintained through education and implementation of current infection control policies and safety measures.	annul i mal basi i Nikana										-	
DII.8a	Infection control and safety measures for the preparation, dispensing and disposal of pharmaceuticals include but are not limited to:												A de la companya de l
	1) Observation of standard precautions			·									
	2) Adequate hand hygiene/hand washing			<u> </u>									
	3) Procedures for preventing exposure to blood borne pathogens												
	4) Glove, gown and eye shield use while compounding hazardous products and chemotherapeutic substances												
	5) Use of aseptic technique												
	6) Appropriate use of particulate and/or bacterial filtration		-							-			
	7) Hood decontamination practices			ļ									
	8) Venting of the laminar flow hood outside the building or use of a Class II Biological Safety Cabinet when compounding cytotoxic drugs					·							
	9) Proper disposal of needles used in the preparation of pharmaceuticals done by disposing of needles in a tamper proof, puncture resistant container												
	10) Proper disposal for hazardous waste product	5											
DII.8b	When applicable, the home environment is assessed to evaluate potential safety hazards and to instruct the client and/or those associated with the care of the client about safety precautions. The assessment and client teaching is documented in the client's record.												
DII.8c	Disposal of outdated drugs, controlled substances o hazardous wastes is documented and conforms to state and federal requirements.	r											
	1) Controlled substances are returned to the Drug Enforcement Administration if required. Documentation of the disposal of controlled substances on site is witnessed by two individuals and includes the amount and type of the drug.								A.Marian	- ·			

EMPENOE CHINELINES	CITATION STATEMENTS
EVIDENCE GUIDELINES	OTTAL COLUMN TO THE COLUMN TO
D = Documentation S = Survey O = Observation I = Interview	
O = Observation I = Interview	
D: A Material Safety Data Sheet clearly	
outlines protocols for disposal	
of hazardous products. (DII.8c.2)	
O: The Material Safety Data Sheet is	
available in the pharmacy. (DII.8c.2)	
Note: The Material Safety Data Sheet	
information may be available	
on the pharmacy website as long as	
each pharmacy employee has access	
to the information.	
D: Written instructions regarding	
disposition of hazardous substances	
in homes are provided to	
appropriate clients. (DII.8c.3)	
I: Staff and client are aware of	
disposition procedures for	
hazardous substances, if indicated.	
(DII.8c.3)	
D. Records confirm adherence to	
policy and regulation. (DII.8c.4)	
D: Client instructions regarding	
preparation of sterile solutions,	
storage methods, and durations are documented. (DII.8d)	
I: Clients preparing sterile solutions at home are able to describe	
appropriate preparation and	
storage precautions. (DII.8d)	
D: Written infection control and safety	
policies for equipment/delivery	
service are available. (DII.8e)	
D: Policies specify maintenance,	
testing, and repair specifications for	
each type of equipment. (DII.8e)	1980 Company of the C
I & O: Equipment is maintained, tested,	
and repaired according to manufac-	
turer's recommendations. (DII.8e)	
I & O: Staff demonstrate an under-	
standing of infection control procedures and policies. (DIL8f)	
D: Policies specify elements 1 – 5 of	
DI. Policies specify elements 1 = 3 or DIL.8f. (DII.8f)	
D & O: Review of records and	
observation of practice confirms	
adherence to organizational policies	
and that activities are conducted on	
a routine basis. (DII.8f)	

	PHARMACY STANDARDS	Prior Visit NM	SS		Termentum I		ent Visit		COMN	TENTS
	Material Safety Data Information is kept in the pharmacy and identifies procedures for disposal of hazardous products			NA	Met	Com	NMI RA	Rec		
	3) Clients are instructed regarding the proper disposal of hazardous products in the home					·			•	
	4) Records are maintained, as required									
DII.8d	When clients and caregivers prepare sterile preparations in the home, they are instructed verbally and in writing regarding safeguards against microbial contamination, including, but not limited to the following:	·								
	1) Instructions regarding the preparation of the sterile solution									•
	2) Storage methods									
	3) Duration and stability of the prepared solution									
DII.8e	Infection control and safety control policies are established and implemented for the equipment/delivery service, including:						и 1			
	Maintenance, testing and repair of equipment according to manufacturer's guidelines		-							
	2) Cleaning and storage of reusable equipment between usage									
	3) Inspection of equipment prior to delivery.									
DII.8f	The Pharmacy Program that prepares compounder sterile products conducts the following activities on a routine basis:									
	Routine disinfection and quality testing of direct compounding environment									. * - *
	2) Visual confirmation of personnel processes regarding gowning, and other infection control/safety measures									
Management of the second secon	Review of orders and packages of ingredients to assure correct identity and amounts of ingredients	3								
	4) Visual inspection of compounding sterile products									
	5) Media-fill test procedure performed at least annually for each person									·
DII.9	Client complaints and concerns are responded to and resolved in a timely manner.									* · · · · ·
DII.9a	The complaint process includes:			L						

	EVIDENCE GUIDELINES	CITATION STATEMENTS
	D = Documentation S = Survey O = Observation I = Interview	
D:	Documentation validates that the complaint process includes elements 1-9. (DII.9a)	
D:	Review of complaint log validates that complaints have been responded to consistent with the organization's policy and process. (DII.9a)	
	(DH.9a)	

	PHARMACY STANDARDS	Visit NM	SS		Curre	nt Visit	COMMENTS
		14141		NA	Met Com	NM RA Rec	
maderalis ha (paners) à cui inté cu	Designation of the individual(s) responsible for responding to the complaint						
	2) Procedures for responding to complaints						
	3) Time frame for responding to complaints						
	4) Assurance that corrective action is taken as appropriate						-
	5) Assurance that client and family rights are protected						
	6) Follow-up activities						
	7) Resolution of the complaint						
	8) Complainant is informed of the outcome						
\ 	9) Trending of justified complaints						

	EVIDENCE GUIDELINES	CITATION STATEMENTS
	D = Documentation S = Survey	man and the second seco
	$O = Observation \qquad I = Interview$	
	Staffing assignments are available. (DIII.1a)	
	Mechanisms for evaluating workload demands are described. (DIII.1a)	
I:	Mechanisms for employee selection are described. (DIII.1b)	
	Documentation of required elements 1-10 validates compliance and inclusion in the personnel files, health files, or the administration files. (DIII.1b)	
D:	Records include diplomas/ transcripts, current licenses and continuing education attendance (if required) for all clinical/ professional staff. (DIII.1b.3,4,5)	
D:	Documentation of certification or adequate training is available for pharmacy technicians and delivery personnel identifying training provided for all tasks performed by the technician and the driving personnel. (DIII.1b.6, 8)	
I:	Delivery and equipment service personnel selection process is described, including driving record checks, and compliance with relevant motor carrier safety regulations. (DIII.1b.7)	
I:	Mechanisms for assessing and updating clinical competencies/skills are described. (DIII.1c)	
D:	Documentation of clinical competency/skill assessment at time of hire and annually thereafter is	
	available. (DIII.1c)	
	· ·	

	•	PHARMACY STANDARDS	Prior Visit NM	SS	-	Current Visit	COMMENTS
ŀ		See 19 1 See 1.			NA	Wet Com NW RA Rec	
N. St. Land		ADBROJUAGIEGRESGURÇES PHUMAN 11. P	**************************************				
		The Pharmacy organization has adequate and appropriate human resources to meet workload demands.					
		Staffing guidelines are developed and implemented to adequately meet workload demand.					
	DIII.1b	Qualified personnel are recruited and retained. Documentation is found in the personnel files, health files or administration files of the following:					
		Budgets allocate sufficient funds to ensure staffing at all levels and are maintained to adequately meet workload demands					* *
		 Positions, new and vacant, are filled on a timely basis to sustain organizational performance goals 					
		Clinical staff show evidence of graduation from colleges approved or accredited by their respective professional organization					
		4) Clinical staff maintain and show evidence of current licensure					
		5) Clinical staff show evidence of continuing education when required					·
		6) Pharmacy technicians show evidence of certification, or have evidence of adequate training, for all tasks performed in conformance with applicable laws					
		7) Delivery personnel, when utilized, have a clean driving record and maintain a current driver's license					
		Delivery personnel, when utilized, show evidence of adequate training for all tasks performed			-		
	To a local l	9) Professional & technical personnel show evidence that professional skills are assessed and updated					
		10) Compounding personnel show evidence of skills, training, and competency testing to perform and document compounding duties.	1000				
	DIII.1c	Clinical competency evaluations are performed to assess employee basic skill levels for all staff providing client care/services:					
		1) At time of hire	- Pro-				
		2) Annually, thereafter					

	EVIDENCE GUIDELINES	CITATION STATEMENTS
	D = Documentation S = Survey	
	O = Observation I = Interview	
D:	Documentation of clinical competency assessment including	
	elements 1-5 at time of hire and annually thereafter is available. (DIII.1d)	
I:	Mechanism for assessing clinical competency is described by manger and pharmacy personnel. (DIII.1d)	
D:	An orientation plan is available and includes elements 1-5. (DIII.1e)	
D 8	E I: There is an appropriate supervision plan for all levels of staff and each employee. (DIII.1f)	
D:	Records show documentation of state/organizational required in-service attendance by pharmacists. (DIII.1g)	
	Note: In-services may be provided by the organization or other approved entities.	
D:	Records show documentation of organization's provision of annual in-service/continuing education	
	program and pharmacist's attendance at the in-service/continuing education session.	
	(DIII.1h)	
I:	Pharmacy Director describes mechanism for assuring	
	compliance with responsibilities. $(DIII.2)$	

	PHARMACY STANDARDS	Prior Visit NM	SS		Current Visit	COMMENTS
				NA	Met Com NM RA F	Rec
DIII.1d	Clinical competency evaluations of pharmacy personnel who use laminar flow hoods and/or Class II Biological safety cabinets are conducted at time of hire and annually thereafter and include at a minimum:					
	Written test to verify employee's understanding of the concepts of aseptic technique					
***************************************	2) Observation of employee's aseptic technique					
	3) Sterility validation testing for all employees who make sterile products					
	4) Observation of cleaning, testing and calibration of infusion equipment					
	5) Observation of cleaning, testing and calibration of compounding equipment					
DIII.1e	The orientation plan addresses at a minimum:					
***************************************	1) Mission statement			-		
	2) Organizational Chart		†	\		
	3) Lines of authority and responsibility		1			
***************************************	4) Job related responsibilities (job description)	·				
	5) Human Resources policies/conditions of employment					
DIII.1f	There is adequate supervision of all pharmacy personnel.					
-	Professional Pharmacy services are provided by or under the direction and supervision of a qualified Pharmacist.					
	2) Staffing ratios of pharmacists to pharmacy technicians are in compliance with state regulations.					
DIII.1g	Pharmacists show evidence of participation in formal in-service programs required by state regulation and organization policy.					3,000 J. J. J. J. J. J. J. J. J. J. J. J. J.
DIII.1h	The organization provides a minimum of one medication safety in-service annually					
DIII.2	Formal-written contracts and agreements with other organizations and/or individuals for the provision of pharmacy products and services to pharmacy organization clients detail specific responsibilities of the parties involved.					

EVIDENCE GUIDELINES	CITATION STATEMENTS
D = Documentation S = Survey	
O = Observation $I = Interview$	
D: Contracts for pharmacy services	
contain all elements in	
CIII.2a-b, DIII.2a and DIII.2b. (DIII.2a, DIII.2b)	
I: Pharmacy Director describes mechanism for assuring	
compliance with responsibilities.	
(DIII.2)	
•	

	PHARMACY STANDARDS	Visit NM	SS		Current Visit		COMMENTS
				NA.	Met Com NM RA	Rec	
DIII.2a	Formal written contracts and agreements with other organizations and/or individuals for provision of pharmacy services includes specific responsibilities as defined in CIII.2a-b and, in addition, the following specific responsibilities:			T T			
	Which organization has the authority to accept and terminate client services						
	2) Services provided under contract must be in compliance with professional standards						
	The manner, in which products and services will be controlled, coordinated and evaluated						
	4) Designation of responsibilities for orientation						
DIII.2b	Pharmacy services when provided under arrangement are in accordance with CHAP Pharmacy Standards and are in compliance with CIII.2a-b, DIII.2a and, in addition, include the provisions for:						,
	Who is responsible for teaching the client about pharmaceuticals						
	2) Assurance that personnel meet the pharmacy program's educational and training requirements						
name de la constanta de la con	Maintenance of current licensure and certification where required	,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,					
	4) On site supervision of pharmacy personnel						
,	5) Hours when pharmaceutical services are available to the client, including arrangements for services during "off hours"						
	6) Time frames for response to new referrals						
	7) Responsibilities of contractor and contractee, including:					**************************************	
	(a) Who assesses the need for pharmaceuticals						
	(b) Who contacts the pharmacy						
	(c) Who obtains the written physician order	s					
	(d) Who generates drug profiles and to whom they will be made available of those involved with the client's care						
	(e) Who maintains records for investigations drugs and controlled substances	ıl					•

	EVIDENCE GUIDELINES	CITATION STATEMENTS
	D = Documentation S = Survey	
	O = Observation $S = SurveyO = Observation$ $I = Interview$	
D:	Contracts for delivery services contain all elements in CIII.2a-b, DIII.2a and DIII.2c. (DIII.2c)	
D:	Policies pertaining to cash management and contingency planning are available. (DIII.3a)	
I:	Pharmacy Director describes how the organization manages its cash and cites examples of contingency planning. (DIII.3a)	
D&	I: Pharmacy Director and/or Financial Manager describe and document the insurance coverage and discuss the rationale for the amounts. (DIII.3b)	
D:	New Pharmacy product/service plan proposals include specified elements. (DIII.3c)	
I:	Management team describes examples of recognition of inter- relationship of finance, quality, product and service operations. (DIII.3d)	
O:	Observation of the physical facility	
٠,	validates that elements 1 -7 are in evidence and in conformance with state/federal requirements.	
	(DIII.4a)	
		·

		PHARMACY STANDARDS	Prior Visit NM	SS					COMMENTS			
-		(f) Procedure to follow assuring the			NA	Met Com	NM RA R	ec	,			
		availability of drugs and supplies to the clients in their home when not available from the pharmacy										
)	(g) Mechanisms for evaluating the contracted service						, , , , , , , , , , , , , , , , , , , 				
I		Delivery of products and supplies when provided to clients under arrangement are in compliance with CIII.2 a-b, DIII.2a and, in addition, include the provisions for:						•	,			
		Ensuring clean and safe transport of equipment and supplies										
		2) Timely delivery of products and supplies										
		3) Setting up equipment in client's homes, where appropriate			ļ							
-		4) Adequately trained delivery personnel										
		5) Client education, where appropriate						·>···				
.,,	***************************************	6) Appropriate documentation										
		The Pharmacy Organization/Program has adequate and appropriate financial resources to meet its stated mission.										
	OIII.3a	The organization has a contingency plan and/or policies and procedures to adequately address cash or operating short falls that may impact the products and services it provides.	American control of the second control of th									
	DIII.3b	Insurance coverage is maintained for the loss due to general liability, product liability, professional liability and work related injuries.										
	DIII.3c	New program, product or service planning and development occurs prior to implementation which includes analysis of effectiveness and profitability of the project.				:						
	DIII.3d	The management team's performance reflects an understanding of the interrelationship of finances, quality, product and service operations and long term viability of the organization.			•							
	D101.4	The Pharmacy organization has adequate and appropriate physical facilities to accomplish its stated mission.						B &				
	DIII.4a	The Pharmacy organization has the necessary space, equipment and supplies for safe preparation dispensing, storage and delivery of pharmaceutical in compliance with state and federal requirements, and includes at a minimum:	s									
						PO-NAME N	1.646.0015,544	L				

	- Company Dieg	CITATION STATEMENTS
	EVIDENCE GUIDELINES	CHAILON DIMES
	D = Documentation S = Survey O = Observation I = Interview	
	U = Observation 1 - Interview	
D:	Written policies specify elements 1-5.	
	(DIII.4b)	
Δ.	Work surfaces and equipment are	
U:	cleaned and disinfected in	
	compliance with pharmacy policy.	
	(DIII.4b)	
	The Comment	
	Note: Compounding environment includes walls and floors.	
	(DIII.4b.2)	
D,I	&O: Interview, observation and	
	review of reference data validate that professional/community	
	standards of practice are followed.	
	(DIII.4c)	
	7*1 / /l - / - / - / - / - / - / - / - / -	
O:	Observation validates that sterile and non-sterile preparation areas	
	are separate and adequate.	
	(DIII.4d)	
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	PHARMACY STANDARDS	Visit NM	SS		Curre	nt Visit	COMMENTS
				NA	Met Com	NM RA Rec	
	Designated area for preparation of sterile products for dispensing						
	2) Hot and cold running water with sink						
	3) Walls, ceilings and floors made of non-porous cleanable surfaces						
	4) Accurate balance and measuring devices						
	5) Adequate ventilation and lighting						
	6) Disposable hand drying towels						
	7) Adequate storage facilities						,
	(a) Parenteral compounding items stored to maintain integrity of aseptic environment						
	(b) Adequate refrigerator/freezer capacity to meet storage requirements for all refrigeration-required materials.						
	(c) Shelves and storage containers made of washable, non-porous materials, including non-use of corrugated cardboard/styrofoam						
DIII.4b	The Pharmacy organization maintains adequate and clean compounding areas in compliance with its policies which specify:						
	The adequacy of workspace per state regulations						
	2) Frequency, types of cleaning agents and procedures of how work surfaces, equipment and compounding environment are cleaned and disinfected						
	3) Work surfaces are kept free of equipment, supplies, records and other material unrelated to the preparation of a given drug					1.1	
	4) Certification of laminar flow hood per organizational policy and/or state/federal regulation	n					
	5) Validation of cleaning and compounding practice including surface sampling, environmental air sampling and end product sterility testing for pyrogens.						
DIII.4c	Storage of the final pharmaceutical product is in accordance with acceptable professional/community standards of practice which are supported by reference data, including temperature, light and length of time.	,					
DIII.4d	Areas for compounding of sterile products are functionally separate from areas for the preparation of non-sterile products and are constructed to minimize opportunities for contamination of products.						

	EVIDENCE GUIDELINES	CITATION STATEMENTS
	D = Documentation S = Survey	
	O = Observation I = Interview	
	e: Observation of injectible drug work areas and review of end product testing results validate compliance with the specifications	
	designated in elements 1-3. (DIII.4e)	
D:	Documentation of semi-annual inspections and pre-filter changes as required is available. (DIII.4f)	
D:	Certification reports from the most current three year period are available. (DIII.4f)	
1&	O: Pharmacy personnel are knowledgeable of and use	
;	appropriate techniques when using a hood or cabinet. (DIII.4g).	
I&O	e: Interviews with staff and observation of practice confirms	
	compliance with policies. (DIII.4h, DIII.4i, DIII.4j)	
D:	Written policies specify elements 1-5. (DIII.4k)	· .
O:	Products are shipped in compliance with the pharmacy's policy.	
	(DIII.4k)	
	•	

	PHARMACY STANDARDS	Visit NM	ss		Curre	nt Visit	COMMENTS
DIII.4e	There are adequate work areas for the preparation and manipulation of injectable drugs, which includes the following:			NA	Met Com	NM RA Rec	
	Methods for inspecting ingredients and final products for the presence of inappropriate particulate matter or signs of deterioration or microbial contamination	,					
	2) Use of laminar flow hoods						
	3) Use of Class II Biological Safety Cabinets for the preparation of cytotoxic drugs						
DIII.4f	Laminar Flow Hoods and Class II Biological safety cabinets are inspected at least every six months and certified by an independent agency that they are operating according to specifications. Certification records are retained for a minimum of three years.						
DIII.4g	Pharmacy personnel using a laminar flow hood or a Class II Biological safety cabinet use proper techniques consistent with professional standards of practice to ensure a continuous aseptic environment during the admixing of sterile pharmaceuticals.						
DIII.4h	Preparation of injectables from sterile solutions includes the use of filters when removing solutions from ampules.						
DIII.4i	Injectables prepared from non-sterile powders are:						
	Dissolved in sterile solution for injection						
	2) Filtered through a 0.2 micron filter.						-
DIII.4j	Respiratory medications prepared from non-sterile powders are prepared in an ISO 5 environment and are:						
	1) Dissolved in sterile solution						
	2) Filtered through a 0.2 micron filter						
	3) Packaged under ISO 5 environment condition	s					
	4) Periodically end product tested	ļ	_	-			_
DIII.4k	Adequate shipping containers and shipping processes are used in accordance with regulations and manufacturers guidelines to assure drug stability and potency which includes the following:						
	Assurance of stability and potency of the products being shipped						
	2) Temperature control						
	3) Non-exposure to light			_l			

	EVIDENCE GUIDELINES	CITATION STATEMENTS
	D = Documentation S = Survey	
	O = Observation I = Interview	
O:	Client service areas are private,	
	clean, safe and in compliance with ADA regulations. (DIII.41)	
	ADA regulations. (Diff-17)	
D:	External databases are available	
	and used for comparison. (DIII.5a)	
D:	Benchmark reports are available.	
ν.	(DIII.5b)	
Note	: Organizations may use internal standards, professional standards of	
	practice guidelines, research findings	
	or professional references to	
	determine benchmarks.	
	O winding multiple sites	
	Organizations may use multiple sites, divisions and/or professional	
	reference data to benchmark against.	
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	PHARMACY STANDARDS	Visit NM	SS		Current Visit		COMMENTS	
				NA	Met Com	NM RA	Rec	
	4) Non-exposure to contaminants							_
	5) Packaging of medications in a tamper evident manner							
DIII.41	The organization's physical facilities provide a safe environment for staff and clients and allow for the efficient provision of services.							
	Space and privacy are adequate for the services being provided						**************	
	Physical facilities and resources permit effective and efficient function of the personnel							
	Provisions are made to accommodate clients and staff with disabilities							
DIIILS	An effective and efficient management information system is utilized to ensure accountability at all levels of the organization.							
DIII.5a	When available, the organization uses external databases that provide information relevant to the organization's products and services and creates a basis for comparative analysis.							
DIII.5b	The organization participates in a benchmarking system.							
	Benchmark data are consistent with organizationally defined goals and objectives							
	2) Benchmark collected data, when available, are measured against data from other organizations							

	EVIDENCE GUIDELINES	CITATION STATEMENTS
	D = Documentation S = Survey	
	O = Observation I = Interview	
D:	The pharmacy operational plan is available. (DIV.1a)	
D:	Governing Body meeting minutes document approval of the initial pharmacy operational plan and changes. (DIV.1b)	
D:	An annual evaluation of the pharmacy organization's program and operations is conducted. (DIV.2)	
I:	Management describes the annual evaluation process and the way it is used for future planning for the organization. (DIV.2a)	
I:	Management personnel describe how the complexity of the organization relates to data collection and utilization. (CIV.2b)	· .
D	E I: Evidence exists that product and service pricing is routinely evaluated. (DIV.2c)	
D:	The interrelationship between the pharmacy program evaluation and the overall organizational evaluation is evident when the pharmacy is part of a larger organization. (DIV.2d)	
O:	Innovations have been developed and implemented. (DIV.3)	
	and implemented (21112)	
	e e e e e e e e e e e e e e e e e e e	

	PHARMACY STANDARDS	Visit	SS		Curren	at Visit	COMMENTS
		NM		NA	Met Com	NM RA Rec	
The state of the s	THE TRANSPORT OF THE PROPERTY		ļ				
1 (4331) 151 (1911) 11 (1911) 12 (1911)	Operational planning reflects the Pharmacy's mission.						
DIV.1a	The planning process focuses on performance						
	expectations and is consistent with organizational needs.						
DIV.1b	The written plan is developed, and the initial plan and changes are approved by the governing body.						
DIV.2	An annual systematic evaluation of major aspects of the Pharmacy Organization's program and operations provides the basis for future planning.						
DIV.2a	Mechanisms are established in writing for the collection, dissemination and use of information for						
	the purpose of management, quality improvement,						·
	planning and future evaluation purposes.						
DIV.2b	Data appropriate to the complexity and scope of the						
D17.20	Pharmacy organization is collected and monitored.						
DIV.2c	Pricing of products and services is routinely evaluated.	<u></u>					
DIV.2d	Results of the Pharmacy organization's evaluation						
	findings are integrated into the corporate organization's report, if applicable.						
DIV.3	The Pharmacy Organization management team fosters innovation within the organization and brings strong leadership to industry-related activities.						
DIV.3a	A common and futuristic vision of the organization is established and sustained.	Lag Lag (Management Lag at 186					
	A learning environment for all staff is promoted and supported						-
	2) Staff development is encouraged						
	3) Governing body members have expertise specific to the enhancement of the organization's mission						
DIV.3b	An atmosphere of mutual respect permeates the organization throughout.						-
	Interaction between staff, administration and governing body is evident and is facilitated						
DIV.3c	The organization has positioned itself to participate in public forums that shape health care policy and educate consumers.						
DIV.3d	The organization actively networks with other providers and provider organizations.						

V

"CHAP" BOARD OF REVIEW SUMMARY

	V Commont	S. CO.																									
2	LT Viability	#C #R/A																			1	Т-		Т	· T		
	Resources	#C #R/A															•	: N =	# Description								
=	Quality	#C #R/A															(yes) (no)	L - Tags: N =	L-Tag#								
	Str.& Function	#C #R/A															Deficiencies:		Description								
ummary	II. Category	Standards	Core	Home Health	Hospice	Pvt. Duty	Home Inf.	Public Health	HME	Pharmacy	Community Nsg.	Supp. Staffing		Totals			III. Medicare	.G - Tags: N =	G-Tag#s.								
Board of Review Action Summary	I. Meeting Date:	Agency Name:		Address:				Date of Site Visit	Type of Visit:	Initial visit with ss	Annual, 1st yr. of cycle w/SS	Yr. 2, Yr. 3	Focus Complaint f/u	Reports	Progress Yes No	Due Date	Complaint Resolved	Yes_No	Additional Action Req'd	Yes No	Describe		Legend:	SS: Self Study	C: Commendation	R: Recommendation	

Orig. (3/98) Rev. (12/98) Rev. (6/99) Rev. (5/00) Rev. (1/05)

"CHAP" ' BOARD OF REVIEW SUMMARY

Board of Review Action Summary: cont'd.		Progress Report Items to be
		addressed
Meeting Date:		
Agency Name:		
Einel Board Decision		
Progress Report (as applicable)acceptednot accepted		
Accreditation without Required Actions		
Accreditation with Required Actions		
Accreditation with Required Actions &		,
Progress Report due: 30, 60, 90, 120 days		
Accreditation With Required Actions,		
Focus visit in 30, 60, 90, 120 days		
Defer Accreditation (initial accreditation only)		
Formal Warning (continued accreditation only)		
Deny Accreditation (initial accreditation only)		
Withdrawal of Accreditation (continued accreditation only)		
NEXT VISIT:	***************************************	
Focus Visit	Former Required Actions Met	
12 months		ţ
18 months	Former Required Actions Continuing	6um

Reviewer's Signature

Contract Cycle

Orig. (3/98) Rev. (12/98) Rev. (6/99) Rev. (5/00) Rev. (1/05)

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Community Health Accreditation Program, Inc. 1300 19th Street NW, Suite 150 Washington, DC 20036 t: 202-862-3413 f: 202-862-3419 web: www.chapinc.org

Accreditation Site Visit Report

Name of Organization:				
Address:				
Legal Structure:			·	
Services Accredited:				
Provider #s:			•	
Principals:				
Telephone #: Fax #: Email #				
Site Visit Date(s):	• .			
Site Visitors:				
Accreditation Status:				
Board of Review Dates:	February 9 – 10, 200)6		
Site Visitor Recommendation:				
Board of Review Determination:	:			

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SUMMARY

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ORGANIZATIONAL STRENGTHS

ORGANIZATIONAL CHALLENGES

COMMENDATION (S) N=

DEFINITION:

A statement that indicates an organization has EXCEEDED the requirements of a specific standard.



RECOMMENDATION (S) N=

DEFINITION:

A statement that identifies a potential problem with a given standard

that may increase in scope and severity if not addressed. A

recommendation should be given serious

consideration by the Agency, but changes are not mandatory.

REQUIRED ACTION (S) N=

A statement that indicated non-compliance with CHAP Standards or Criterion.

REQUIRED ACTION (S) NOW MET=